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LEXSEE 1985 US DIST LEXIS 19169

McNeilab, Inc., Plaintiff, v. Margaret M. Heckler, Secretary, Department of Health and Human Services, et al., Defendants

Civil Action No. 84-1617

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

1985 U.S. Dist. LEXIS 19169

June 5, 1985, Filed

LexisNexis(R) Headnotes

OPINIONBY: [*1]

FLANNER

OPINION:

MEMORANDUM

THOMAS A. FLANNER, UNITED STATES DISTRICT JUDGE

This matter comes before the court on the parties' cross-motions for summary judgment and a motion by defendant-intervenors for reconsideration of the court's August 31, 1984 Memorandum and Order granting plaintiff standing to pursue this action. For reasons discussed herein, the motions of defendant and defendant-intervenors for summary judgment will be granted, and the motion for reconsideration will be denied.

I. Background

Plaintiff McNeilab, Inc. is a corporation engaged in developing, manufacturing, and selling various pharmaceutical drugs, including the acetaminophen-based pain reliever TYLENOL. On May 18, 1984, defendant Food and Drug Administration ("FDA") approved New Drug Applications ("NDAs") for over-the-counter ("OTC") sale of the drug ibuprofen, a pain killer not previously available without a prescription, by defendant-intervenors Bristol-Myers Co., Upjohn Co. and American Home Products Corp. ("AHP"). Those manufacturers market ibuprofen under the trade names NUPRIN and ADVIL. Plaintiff brought suit, claiming that the FDA had exceeded its statutory authority in approving the NDAs because [*2] that approval had been conditioned on the inclusion by Bristol-Myers, Upjohn and AHP of certain statements in the advertising for OTC ibuprofen.

According to plaintiff, various decisionmakers at FDA determined that ibuprofen posed a sufficient danger to that portion of the population which is aspirin-sensitive that the FDA was not willing to approve the drug for OTC sale based on warnings contained in the label alone. Rather, McNeil contends, the FDA decided that ibuprofen could be made sufficiently safe for OTC sale if, in addition to the warnings on the label, the manufacturers were also required to include certain statements regarding, among other things, aspirin sensitivity in the advertising for the drug once it entered the OTC market. The FDA, McNeil points out, is empowered to approve an NDA only if a drug is safe and effective for use "under the conditions . . . prescribed, recommended, or suggested in the proposed labeling thereof." *21 U.S.C. § 355*(d)(5). Therefore, plaintiff contends, the conclusion that advertising restrictions were necessary to make ibuprofen safe and effective for OTC sale precludes OTC approval because, by definition, an OTC drug is one which is sufficiently [*3] safe that its use can be controlled by means of the

information on its label alone. Plaintiff also argues that, in addition to being beyond the statutory authority of FDA, consideration of advertising content or imposition of advertising conditions by FDA illegally intrudes into the statutory jurisdiction of the Federal Trade Commission, so that the NDA approvals should be barred on that basis as well. Plaintiff seeks an order declaring the NDAs invalid, as well as an injunction directing defendants to rescind their approval of the NDAs.

Essentially, defendants and intervenors respond that the FDA is empowered to look at the whole marketing "environment" in deciding whether a drug may be safely made available for OTC sale as labeled. Because a drug otherwise safe and effective as labeled could be rendered unsafe by advertising which "undercuts" its labeling, they argue that FDA's examination and review of proposed advertisements was proper as a means of determining whether the proposed labeling would be adequate to permit approval of NDAs for OTC sale of ibuprofen. Rather than imposing advertising requirements as a "condition" for NDA approval, as McNeil contends, defendants argue [*4] that FDA only made "suggestions" to the manufacturers about advertising content, and approved the NDAs solely on the basis of FDA's conclusion that ibuprofen was safe and effective for OTC sale as labeled. Defendants do not deny that this determination was made in light of the advertising standards to which the makers of NUPRIN and ADVIL promised to adhere.

II. Discussion

As a preliminary matter it should be made clear that the FDA's authority to regulate labeling does not extend to the print or television advertisements over which plaintiff contends defendants attempted to exercise control. FDA's authority to control labeling extends only to "literature" which "supplements" a drug's package label and which is "distributed to consumers as part of an integrated distribution program" and "constitutes an essential supplement to the label attached to the package containing the drug although this literature may have been shipped separately and at a different time than the drug." See *Kordel v. United States, 335 U.S. 345, 349-50, 69 S. Ct. 106, 109-10 (1948); Alberty Food Products Co. v. United States, 185 F.2d 321, 324-25 (9th Cir. 1950).* This court cannot conclude that newspaper [*5] or television advertisements "accompany" intervenors' products or are "distributed" by retailers to ultimate purchasers of the drug as part of an "integrated distribution program." See *Alberty Food, 185 F.2d at 325;* see also *United States v. 24 Bottles "Sterling Vinegar and Honey Ages in Wood Cider Blended with Finest Honey Contents 1 Pint Product of Sterling Cider Co., Inc., Sterling, Mass.", 338 F.2d 157, 158-59 (2d Cir. 1964).* Therefore, to the extent that defendants influenced the content of ibuprofen advertising, their authority to do so cannot be said to derive from FDA's authority to control the contents of drug labeling.

Having framed the issue as one of the FDA's authority to consider and influence advertising as opposed to the agency's unquestioned power to control the contents of drug labeling and packaging, the outcome of this case depends on how one views the outcome of the process which resulted in the approval of the NDAs. On one view of the record in this case, the FDA determined that information contained in the labeling alone could make ibuprofen safe and effective for OTC sale, and examined the proposed advertisements only to determine whether they would [*6] undercut the safety information contained in the drug's labeling, and thus render the drugs "misbranded." Such an examination would appear to be proper under the Third Circuit's analysis in *United States v. Article of Drug Designated B-Complex Cholinos Capsules, 362 F.2d 923, 925-27 (3d Cir. 1966).* On the other hand, plaintiff contends that the record demonstrates that warnings on the use of ibuprofen in the labeling alone were deemed insufficient to make the drug safe for OTC sale, and FDA concluded that ibuprofen could be made safe by requiring warnings in advertisements to "supplement" the label. Approval of the ibuprofen NDAs under that standard, it seems clear, would be beyond the statutory authority of the FDA. See *21 U.S.C. § 355.*

Plaintiff concedes that, as a general matter, FDA has the authority to consider the advertising "environment" in determining whether to grant or deny NDA approval for OTC sale of a drug. As FDA points out, section 505(d)(6) of the Food, Drug & Cosmetic Act requires that the agency refuse to approve an NDA if the proposed labeling is false or misleading "based on a fair evaluation of all material facts." *21 U.S.C. § 355*(d)(6). Similarly, [*7] section 505(d)(4) of the Act provides that in determining whether a drug is "safe for use" under the conditions proposed, the FDA may consider both the information submitted as part of the NDA and "any other information before [the Secretary] with respect to such drug . . . ." *21 U.S.C. § 355*(d)(4).

Although McNeil thus concedes that some awareness of intended advertising content by FDA is permissible, plaintiff contends that FDA's only remedy for an advertising "environment" which jeopardizes the effectiveness of a drug's labeling is not to discuss problems with the ads with the applicant, but rather to prohibit OTC sale of the drug. See McNeil's Reply Brief at 1-2. Yet if the FDA can consider the types of advertisements a manufacturer intends to utilize in deciding whether to approve an NDA, it would be absurd

to preclude the FDA from telling a manufacturer what it was about a proposed advertisement that would require the agency to deny NDA approval. A proscription against "altering the advertising environment," which McNeil advocates, would place drug manufacturers in the untenable position of having their NDAs rejected due to advertisements that the FDA deems misleading **[*8]** in some manner, and being forced to revise their advertising campaigns blindly until, whether by clairvoyance or good fortune, they happened upon a campaign which the agency was satisfied would not undercut or contradict the proposed label warnings. The court holds, therefore, that communication between the FDA and drug manufacturers regarding the content of advertisements and their effect on the safe and effective use of a drug as labeled is not prohibited by the Food, Drug and Cosmetic Act.

Although communication between FDA and manufacturers is appropriate, it is nevertheless clear from the Act that the warnings and directions on a drug's label are the focal point in the FDA's determination of safety and effectiveness for purposes of NDA approval. Therefore, if the agency determines that a drug cannot be safely marketed as labeled, it cannot approve an NDA for OTC sale. The agency cannot rely on advertising to make safe a drug which is deemed too dangerous to be sold with label warnings alone. After thoroughly reviewing the administrative record, however, the court is unable to conclude that FDA determined that OTC ibuprofen could only be made safe by imposing advertising requirements **[*9]** on manufacturers to reinforce label warnings that, by themselves, would be inadequate.

As a starting point, the court must first look to the agency's official statements in the Summary Basis of Approval ("SBA") issued for NUPRIN and ADVIL. In those documents, the agency clearly states its concern that "promotional information . . . not counteract the important safety information in the consumer labeling." Administrative Record at 38, 83. Given the manufacturers' assurances that certain information would be included in the advertising for the drugs, the agency explicitly concluded that "the consumer labeling for this product will provide adequate information for the safe use of the product without the supervision of a physician." Id. It thus appears that the FDA was concerned only that ibuprofen advertising not undercut, or "counteract," the drug's labeling. Since the court has concluded that it is proper for the agency to work with manufacturers to ensure that ads do not undercut otherwise sufficient labeling, any changes in advertising or assurances received from the manufacturers as a result of the agency's concerns do not demonstrate that the FDA exceeded its authority in approving **[*10]** the NDAs for OTC ibuprofen.

Even assuming for present purposes that it is proper for the court to examine all of the supplementary documents submitted by defendant which relate to the discussion of ibuprofen advertising, the court is unable to conclude that they provide sufficient evidence that the FDA improperly imposed advertising "conditions" on its approval of OTC ibuprofen. On the one hand, it is clear that certain members of the Arthritis Advisory Committee (AAC) believed that ibuprofen would be unsafe for OTC sale based on the warnings in the label alone, and that warnings in consumer advertising would need to be included to make the drug sufficiently safe for OTC sale. See, e.g., Plaintiff's Exhibit 3, at 210, 217-19. Indeed, it could fairly be concluded from the reservations expressed by members of the Committee that their recommendation for OTC approval was conditioned on FDA's ability to impose a requirement that certain warnings be included in ibuprofen advertisements as well as in the drug's labeling. See id. at 217-19; Plaintiff's Exhibit 4, at 11; Plaintiff's Exhibit 5, at 6, 8, and 9. But even that conclusion is not free from doubt, given the existence of other **[*11]** documents in the supplemental record which indicate that the AAC was concerned with advertising only to the extent that the ads might "undercut important label warnings." See Plaintiff's Exhibit 6 at 139. As stated in a draft of a letter from FDA Commissioner Novitch to the FTC,

> Although the Committee believed that ibuprofen would be safe and effective for OTC use when used as labeled, the Committee expressed deep concern that overpromotion of ibuprofen in the mass media could mislead consumers into thinking that ibuprofen was 'perfectly safe' that, consequently, there was no need to read the 'fine print' on the label. Accordingly, the Committee recommended that ibuprofen be approved for OTC use conditioned on assurances that the drug's advertising would contain appropriate disclosures.

Plaintiff's Exhibit 11, at 118 (emphasis in original).

In sum, while a number of intradepartmental memos and other predecisional documents indicate an apparent belief by some individuals that ibuprofen is sufficiently dangerous that advertising warnings would be necessary in addition to the warnings on the drug's label, other documents indicate a concern that proposed advertisements **[*12]** be examined only to make sure that they do not "soft-peddle" the drug's dangers to certain potential users. Compare Plaintiff's Exhibit 34 ("short warning" in advertisements necessary "to scare people enough so they'll read the full label before use") with Plaintiff's Exhibit 14, at 104 ("FDA's interest was in

learning about the companies' overall promotional plans so that the agency could decide if such promotion was likely to undercut the warnings and restrictions contained in the product's labeling").

It is indisputable that the FDA's concerns with ibuprofen were referred to by one individual as "approval conditional," see Plaintiff's Exhibit 8, and were sometimes expressed in terms of the FDA's "regulation" of OTC consumer advertising, see Plaintiff's Exhibit 20; Plaintiff's Exhibit 23 at 53. Further, the record shows that the FDA's concerns with consumer advertising resulted in detailed examination of proposed advertisements, including the development of several "standards" by which advertisements were measured. See Plaintiff's Exhibit 36, at 71, 76; Plaintiff's Exhibit 37, at 250; Plaintiff's Exhibit 38, at 97, 101; Plaintiff's Exhibit 39, at 243; Plaintiff's **[*13]** Exhibit 41, at 125 (discussing advertising standards, "requirements"); Plaintiff's Exhibit 48, at 99 (advertising submission "was discussed page by page"; major revisions listed).

Yet the existence of these documents does not mandate a conclusion that the FDA has exceeded its authority in approving the ibuprofen NDAs. First, references to adherence to the FDA's standards as "conditions" or "requirements" of NDA approval are not made by FDA decisionmakers; rather, they are made by subordinates who do not necessarily speak for the agency. To that extent, they are not even properly part of the administrative record. More importantly, however, the existence of these scattered references is insufficient to overcome the agency's stated conclusion that the various standards devised by the FDA and the agreements on advertising content that were reached were not "conditions" of NDA approval. In other words, a manufacturer's decision to renege on its commitment to adhere to the FDA's guidelines would not appear to provide grounds for revocation of the NDAs except possibly to the extent that new advertisements contradict the label warnings or advocate a use for which ibuprofen is not approved. **[*14]** Various internal documents cited by plaintiff itself appear to indicate FDA's acknowledgement that the commitments it obtained were voluntary and largely unenforceable following approval of the NDAs. See Plaintiff's Exhibit 9; Plaintiff's Exhibit 12, at 147; Plaintiff's Exhibit 13, at 93; Plaintiff's Exhibit 15, at 107.

Therefore, to the extent that the FDA's line-by-line review and revision of the submitted advertisements exceeded the agency's authority to examine proposed advertising to determine whether it threatens to undercut proposed labeling, such error can be deemed harmless. As stated earlier, the FDA does not exceed its authority when it communicates its concerns regarding advertisements which would preclude NDA approval due to their effect on otherwise sufficient label warnings. When the agency discusses proposed advertising with a manufacturer, however, it should not extend its comments to advertising content which does not have a negative impact on the warnings or other information contained in the drug's labeling. The FDA has no authority to act as "advertising czar" over consumer drug advertising--at most, the agency may discuss aspects of an ad campaign which **[*15]** threaten to undercut the label warnings of a drug which could otherwise be marketed safely as labeled. While it may be persuasively argued that more extensive involvement in "preclearing" consumer advertising would be in the public interest, any attempt to coerce compliance with advertising guidelines which go beyond the FDA's narrow concerns in the area of consumer advertising would be beyond the agency's authority and intrude upon the jurisdiction of the Federal Trade Commission. See *American Pharmaceutical Association v. Weinberger, 377 F. Supp. 824, 831 (D.D.C. 1974)*. In this case, the agency has found that ibuprofen is safe for OTC sale based on its labeling alone. Both the agency and the manufacturers appear to be aware that all commitments regarding advertising are voluntary; indeed, except to the extent that some future advertisement contradicts label warnings or recommends a use for which ibuprofen has not been approved, it is likely that the FDA would be powerless to demand a change. Therefore, to the extent that FDA obtained assurances prior to the NDA approvals regarding advertising content over which the agency lacked authority, any standards agreed to are nonbinding, **[*16]** and a manufacturer's refusal to comply with them would not have provided grounds for rejecting its NDA.

In an appropriate case, it may be so clear that commitments obtained by the FDA in areas beyond the agency's authority acted as prerequisites for NDA approval that it would be impossible for a court to determine that the agency had not relied on impermissible factors. Further, the court rejects FDA's implicit argument that the court is precluded from looking to the record underlying the agency's decision to approve an NDA to determine whether the agency did, in fact, impose conditions on approval which are beyond the agency's authority. FDA has no right to put manufacturers to the Hobson's choice of either accepting "recommendations" for actions which the agency could not require, or facing rejection of their NDAs. See Plaintiff's Exhibit 9, at 208, para. 3. Agency decisionmakers may not avoid the responsibility for a structure of "approval conditional" commitments obtained by subordinates by denying the existence of such commitments in the agency's official decision. After reviewing this record, however, the court is unable to conclude that the agency's decision to approve **[*17]** the NDAs for OTC ibuprofen is so imbued with ultra vires

advertising requirements that the NDAs must be declared invalid.

Based on this holding, and the absence of any persuasive reason to reverse this court's decision regarding plaintiff's standing to bring this action, defendant-intervenors' motion to reconsider this court's decision of August 31, 1984, will be denied.

An appropriate Order accompanies this Memorandum.

C

LEXSEE 2002 U.S. DIST. LEXIS 24621

In re PAXIL LITIGATION; THIS DOCUMENT RELATES TO ALL ACTIONS

CASE No. CV 01-07937 MRP

UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA

2002 U.S. Dist. LEXIS 24621

October 16, 2002, Decided
October 18, 2002, Filed; October 21, 2002, Entered

PRIOR HISTORY: *In re Paxil Litig., 2002 U.S. Dist. LEXIS 16221* (C.D. Cal. Aug. 16, 2002).

DISPOSITION: [*1] Defendant's Motion for Reconsideration was granted and Plaintiffs' request for a preliminary injunction was denied.

LexisNexis(R) Headnotes

COUNSEL: For LESLI HAMILTON, KATHERINE KEITH, plaintiffs: Kevin J Yourman, Zev B Zysman, Weiss & Yourman, Los Angeles, CA. Karen Ann Barth, Baum Hedlund Aristei Guilford & Schiavo, Los Angeles, CA. Mary V Schiavo, Ohio State University, Columbus, OH. Donald J Farber, Donald J Farber Law Offices, San Rafael, CA.

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JUDGES: Honorable Mariana R. Pfaelzer, United States District Judge.

OPINIONBY: Mariana R. Pfaelzer

OPINION: MEMORANDUM OF DECISION RE:

Motion for Reconsideration of Order Granting Preliminary Injunction

I. INTRODUCTION

On August 16, 2002, this Court entered an Order for Preliminary Injunction ("Order") in favor [*2] of Plaintiffs barring Defendant Glaxo Smithkline Beecham ("GSK") from continuing to air television commercials that make the claim that its prescription drug, Paxil, is "not habit forming."

In response, GSK filed a Motion to Suspend Preliminary Injunction Pending Appeal on August 19, 2002 and a Motion for Reconsideration on August 21, 2002. Additionally, at the Court's request, the United States Food and Drug Administration ("FDA") filed a supplemental brief on September 5, 2002. Oral argument by the parties and FDA was heard on October 8, 2002.

Having considered all the submitted papers as well as oral arguments, the Court GRANTS Defendant's Motion for Reconsideration and DENIES Plaintiffs' request for a preliminary injunction.

II. DISCUSSION

GSK and FDA have advanced a multitude of arguments in support of the Motion for Reconsideration, some of which are essentially repetitions of those advanced in prior filings. The Court deems only three of the arguments raised as requiring further comment.

A. Preemption

FDA and GSK assert that the Court's ability to pass judgment upon prescription drug direct to consumer advertisements is limited by the Supremacy Clause of [*3] the United States Constitution. The comprehensive nature of the Food, Drug, and Cosmetic Act ("FDCA"), *21 U.S.C. § 301* et seq., they argue, when taken together

with FDA's expertise, evidences a Congressional intent to preempt state law. Under their theory, control and regulation of these advertisements are within FDA's exclusive domain.

This argument is unpersuasive. To begin with, the parties reveal no case holding that the FDCA preempts state law either expressly or impliedly. If anything, FDA's and GSK's arguments run contrary to the grain of other decisions. See, e.g., *Knoll Pharm. Co. v. Sherman, 57 F. Supp. 2d 615 (N.D. Ill. 1999); Ohler v. Purdue Pharma. L.P., 2002 U.S. Dist. LEXIS 2368, 2002 WL 88945 (E.D. La. 2002); Motus v. Pfizer, 127 F. Supp. 2d 1085, 1092 (C.D. Cal. 2000).*

Further, FDA's and GSK's position vitiates, rather than advances, the FDCA's purpose of protecting the public. That is, FDA and GSK invite the Court to find that in enacting the FDCA for the purposes of protecting public health, Congress not only declined to provide for a private cause of action, but also eliminated the availability of common law state **[*4]** claims. This position contravenes common sense, cf. *Medtronic, Inc. v. Lohr, 518 U.S. 470, 487, 135 L. Ed. 2d 700, 116 S. Ct. 2240 (1996),* and the Court declines the invitation.

B. Primary Jurisdiction

The Court also finds deferral under the doctrine of primary jurisdiction inappropriate. While FDA's expertise in areas such as drug efficacy and side effects cannot be lightly challenged, the Court has not found it necessary to delve into any of those areas. The preliminary injunction does not challenge FDA's finding that Paxil is not clinically addictive nor does it involve labeling, inserts, or material directed to prescribing physicians.

What it does challenge is FDA's and GSK's determination that the public is not likely to equate the words "not habit forming" as used in direct to consumer advertisements with "no withdrawal symptoms." The question of how members of the general public are likely to interpret (or misinterpret) a statement is within one of the courts' core competencies. Nothing here counsels otherwise.

C. Likelihood of Success on the Merits

While the Court is unwilling to blindly accept FDA's ultimate determination here, it **[*5]** has given careful consideration to the extensive fact-finding engaged in by FDA with regard to Paxil and its approval of Paxil's advertisements. Specifically, FDA has now presented evidence to the Court regarding not only the internal review process involved in the advertisements in question, but also its position that the advertisements are not misleading.

Once again, the Court reiterates that in resolving the question presented here, it is not required to decide, nor did it decide, whether Paxil is or is not habit forming. The Court is concerned only with whether in the specific direct to consumer advertisements before the Court, the statement that Paxil is not habit forming could be found to be misleading to consumers.

On this issue, the Court finds FDA's evidence persuasive such that it changes the Court's evaluation of Plaintiffs' likelihood of success on the merits to a degree dictating that the preliminary injunction be denied.

DATED: October 16, 2002

Honorable Mariana R. Pfaelzer

United States District Judge

D

LEXSEE 1998 U.S. DIST. LEXIS 19555

IN RE WARFARIN SODIUM ANTITRUST LITIGATION

C.A. No. MDL 98-1232-SLR, (98 Civ. 1695) (S.D.N.Y.), (97-659) (D. Del.), (97-670) (D. Del.), (98-178) (S.D. Fla.), (98-697) (W.D. Pa.)

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

1998 U.S. Dist. LEXIS 19555; 1999-1 Trade Cas. (CCH) P72,457

December 7, 1998, Decided

NOTICE: [*1] FOR ELECTRONIC PUBLICATION ONLY

DISPOSITION: Defendant's motion to dismiss plaintiff's claims granted in part and denied in part. Defendant's motions to dismiss class plaintiffs' claims granted.

LexisNexis(R) Headnotes

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For Defendants: Philip S. Beck, Esquire, Adam Hoeflich, Esquire, Bartlit, Beck, Herman, Palenchar & Scott, Chicago, Illinois.

JUDGES: Sue L. Robinson, District Judge.

OPINIONBY: Sue L. Robinson

OPINION:

MEMORANDUM OPINION

Dated: December 7, 1998
Wilmington, Delaware

ROBINSON, District Judge

I. INTRODUCTION

This litigation consists of five actions consolidated here by the Judicial Panel on Multidistrict Litigation pursuant to *28 U.S.C. § 1407*(a). Plaintiff Barr Laboratories, Inc. ("plaintiff") originally filed its suit on March 9, 1998 in the Southern District of New York against defendant DuPont Merck Pharmaceutical Company ("defendant"). n1 (D.I. 1 (98 Civ. 1695)) Plaintiff is a generic pharmaceutical manufacturer incorporated in New York with a principal place of business in Pomona, New York. (D.I. 1, P 5 (98 Civ. 1695)) Defendant is a partnership between E.I. DuPont de Nemours & Co. (a Delaware corporation with a principal place of business in Wilmington, Delaware) and [*4] Merck & Co. (a New Jersey corporation with its principal place of business in Whitehouse Station, New Jersey). (D.I. 1, P 6 (98 Civ. 1695)) Defendant manufactures and distributes pharmaceuticals and has its principal place of business in Wilmington, Delaware. (D.I. 1, P 6 (98 Civ. 1695))

n1 By letter dated July 30, 1998, the court was informed that defendant had changed its name to DuPont Pharmaceuticals Company.

Class plaintiffs Kusnerik and Altman filed class action complaints in the District of Delaware, (D.I. 1 (C.A. 97-659) (C.A. 97-670)) while class plaintiffs Tischler and Steckel n2 each filed class action suits against defendant in the Southern District of Florida (D.I. 1 (98-178-Civ.)) and the Western District of Pennsylvania (D.I. 1 (98-697)), respectively (collectively, "class plaintiffs"). Class plaintiffs purport to represent a class of more than 1.8 million persons who purchased Coumadin for personal use at any time during the period beginning on or about July 28, 1997 to the present. (D.I. 1, P [*5] 6 (C.A. 97-659))

n2 Class plaintiff Steckel sued defendants DuPont Pharmaceutical Company, E.I. DuPont de Nemours & Company, and Merck & Company, Inc. For purposes of this memorandum opinion, these defendants shall be referred to in the singular.

In this action, plaintiff and class plaintiffs allege that defendant engaged in unlawful monopolization and attempted monopolization in violation of § 2 of the Sherman Act. *15 U.S.C. § 2*. Plaintiff also asserts claims against defendant founded on § 43(a) of the Lanham Act, *15 U.S.C. § 1125*(a), § 2(c) of the Robinson-Patman Act, *15 U.S.C. § 13*(c), the New York General Business Law, *N.Y. Gen. Bus. L. § § 349* and 350, and common law product disparagement and tortious interference with prospective business advantage. Plaintiff and class plaintiffs seek trebled damages under § 4 of the Clayton Act. Class plaintiffs also seek injunctive relief under § 16 of the Clayton Act. Additionally, class plaintiffs Tischler and Steckel allege that defendant's actions violated [*6] various state laws.

Currently before the court is defendant's motion to dismiss plaintiff's claims and class plaintiffs' claims for failure to state a claim upon which relief can be granted. *Fed.R.Civ.P. 12(b)(6)*. The court has federal question jurisdiction pursuant to *28 U.S.C. § § 1331* and 1337. The court also has supplemental jurisdiction over the state law claims pursuant to *28 U.S.C. § 1367*. For the reasons that follow, defendant's motion to dismiss plaintiff's claims is granted in part and denied in part. Defendant's motions to dismiss class plaintiffs' claims are granted.

II. BACKGROUND

The following facts are taken from plaintiff's and class plaintiffs' complaints and, for purposes of this motion to dismiss, are accepted as true. This suit arises from plaintiff's attempt to market a generic version of defendant's successful and profitable blood thinner known as "Coumadin." Coumadin is the brand name for defendant's formulation of warfarin sodium -- an anticoagulant agent, taken orally, prescribed for patients suffering from thrombosis, embolisms, and other blood-

clotting disorders. (D.I. 1, PP 1, 9 (98 Civ. 1695)) Warfarin sodium (either in generic form or as the [*7] active ingredient in Coumadin) is classified as a Narrow Therapeutic Index ("NTI") drug because too little of it can lead to stroke or cardiac arrest and too much of it can cause internal bleeding. (D.I. 1, P 19 (98 Civ. 1695)) Consequently, treating physicians must carefully monitor patients taking either Coumadin or generic warfarin sodium.

Although the patent protection for Coumadin expired on April 2, 1962, Coumadin has dominated the oral anticoagulant market for over thirty years. (D.I. 1, PP 11, 12 (98 Civ. 1695)) In fact, until plaintiff's generic warfarin sodium tablets were introduced in 1997, no equivalent product competed with Coumadin for several years. (D.I. 1, PP 11, 69 (98 Civ. 1695)) Defendant's annual Coumadin sales are approximately $ 500 million. (D.I. 1, P 24 (C.A. 97-659)) According to class plaintiffs, the cost of Coumadin has escalated 300% to 400% in the past ten years. (D.I. 1, P 25 (C.A. 97-659))

Plaintiff and class plaintiffs allege that defendant, anticipating a loss of market share to plaintiff's cheaper warfarin sodium tablets, n3 "implemented a multifaceted attack against generic substitutes generally and [plaintiff's] product specifically, the cumulative [*8] effect of which has been to raise [plaintiff's] costs to enter the anticoagulant market and to hinder [plaintiff's] ability to penetrate the market effectively." (D.I. 1, P 16 (98 Civ. 1695); D.I. 1, P 33 (C.A. 97-659)) Plaintiff and class plaintiffs contend that defendant engaged in allegedly anticompetitive tactics in order to preserve its monopoly in the oral anticoagulant market. Class plaintiffs claim that, due to defendant's anticompetitive activities, they have paid inflated prices for Coumadin. (D.I. 1, P 51 (C.A. 98-178))

n3 Plaintiff notes in its complaint that

> the introduction of a generic alternative to a brand name product typically results in significant reduction in the brand name product's market share within the first year. The high level of a generic drug's market penetration is due to its lower cost, generic substitution laws, and preferred status in third-party reimbursement plans.

(D.I. 1, P 15 (98 Civ. 1695))

More specifically, in May 1995 plaintiff filed an Abbreviated New [*9] Drug Application ("ANDA") with the FDA seeking approval to manufacture and distribute generic warfarin sodium tablets. (D.I. 1, P 21 (98 Civ. 1695)) In October of 1996, defendant filed a Petition for Stay with the FDA asking it to postpone approval for all generic warfarin sodium products pending the adoption of stricter bioequivalence standards. n4 (D.I. 1, P 22 (98 Civ. 1695)) In its Petition for Stay, defendant argued that the FDA's current bioequivalence standards were inadequate to assure the bioequivalence of Coumadin with other generic warfarin sodium drugs. Defendant asked the FDA to adopt a stricter "individual" bioequivalence standard, rather than an "average" standard, to determine whether generic warfarin sodium products were bioequivalent to Coumadin. n5

n4 Bioequivalence "means the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study." 29 C.F.R. § 320.1 (e) (1998). [*10]

n5 Plaintiff and class plaintiffs characterize this Petition for Stay as "baseless" and designed specifically to inflict competitive injury on plaintiff by forcing it to conduct time-consuming and costly studies before it could enter the oral anticoagulant market. (D.I. 1, P 68 (98 Civ. 1695); D.I. 1, P 33 (C.A. 97-659))

The FDA denied defendant's petition, stating that it was

> in the process of considering individual bioequivalence testing for all generic drugs. At this time, however, it is neither reasonable nor in the interest of the public to impose such testing standards on generic applicants because the approach has not been fully developed and current methods are effective in establishing bioequivalence between drug products.

(D.I. 1, P 29 (98 Civ. 1695) (citing letter from FDA to defendant of 3/25/97, at 3)) The FDA has since issued a request for public comment on a preliminary draft proposal that "recommends that the individual bioequivalence approach be used by sponsors of ANDAs . . . to assess bioequivalence between a generic and a listed drug." *62 Fed. Reg. 67880, 67881* **[*11]** (Dec. 17, 1997). n6

> n6 In ruling on a motion to dismiss, a court may consider only the allegations contained in the complaint, exhibits attached thereto, and matters of public record. See 5A Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure § 1357 (2d ed. 1990). Where, as here, the parties have provided the court with undisputedly authentic regulatory documents, the court may consider them in reviewing a motion to dismiss. See *City of Pittsburgh v. West Penn Power Co., 147 F.3d 256, 259 (3d Cir. 1998);* see also *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192, 1196 (3d Cir. 1993).*

During the same period of time, defendant filed a petition with the United States Pharmacopeial Convention, Inc. ("USP"), urging the USP to adopt Coumadin's narrow content uniformity specifications (which are stricter than those the USP currently requires) as the industry standard for all warfarin sodium drugs. n7 (D.I. 1, P 24 (98 Civ. 1695)) The USP publishes the official **[*12]** compendium of pharmaceuticals in the United States, and listing in the USP is essential to the acceptance of a pharmaceutical product by the medical community. (D.I. 1, P 24 (98 Civ. 1695)) The USP rejected the petition.

> n7 Plaintiff further alleges that defendant's petitioning of the USP to narrow the content uniformity specifications for warfarin sodium tablets was "an obvious attempt to impose stricter regulations on a new competitor" designed to thwart plaintiff's entry into the oral anticoagulant market. (D.I. 1, PP 23, 24 (98 Civ. 1695))

Plaintiff began marketing its warfarin sodium tablets on July 25, 1997. (D.I. 1, P 26 (98 Civ. 1695)) Despite its unsuccessful petitioning efforts with the FDA and the USP, defendant allegedly issued communications setting forth its position that Coumadin is safer and more efficacious than plaintiff's warfarin sodium tablets. It is asserted by plaintiff that:

. Defendant revised its "Couma Care" computer software (a promotional system designed to assist health care **[*13]** practitioners in monitoring patients using Coumadin) to include warnings about switching to generic substitutes. (D.I. 1, P 18 (98 Civ. 1695); D.I. 1, P 35 (C.A. 97-659))

. Defendant created and funded the Health Alliance for NTI Patient Safety to lobby state legislatures, formularies, and pharmacy boards to exclude NTI drugs from state generic substitution laws. (D.I. 1, P 19 (98 Civ. 1695))

. Defendant initiated a publicity campaign touting Coumadin's "tighter than USP" content uniformity standards. (D.I. 1, P 24 (98 Civ. 1695))

. Defendant issued a press release which contained the following assertions:

> if warfarin products are interchanged, patients should receive additional blood tests to ensure the amount of drug in their bloodstream is appropriate for their condition. It should be noted that this warning is included in the FDA-approved package insert for both [defendant's] Coumadin and for [plaintiff's] generic product.
>
> * * *
>
> while [plaintiff] focuses on producing a cheaper product to help save money, [defendant] focuses on patient safety and education and the future health of over two million patients who depend on Coumadin everyday.

[*14]

(D.I. 1, PP 27, 31 (98 Civ. 1695) (citing defendant's press release of 7/28/97, at 2))

. Defendant offered for review to health care professionals a slide presentation in which defendant claimed that, regardless of FDA findings of bioequivalence, generic drugs may not be therapeutically equivalent to their branded counterparts. (D.I. 1, P 29 (98 Civ. 1695))

. Defendant used the FDA's Adverse Drug Event ("ADE") reporting system in order to generate fear over switching from Coumadin to generic warfarin sodium. (D.I. 1, P 35 (98 Civ. 1695)) Specifically, defendant issued a press release in which it stated that "it has submitted to the FDA more than 70 spontaneous reports

from health care providers of adverse drug events temporally associated with patients who had been switched from one drug to the other." n8 (D.I. 1, P 36 (98 Civ. 1695) (citing the press release of 12/3/97, at 1))

> n8 Plaintiff contends that these ADE reports were rife with lies and mischaracterizations and were "designed to defame plaintiff both at the FDA and in the marketplace." (D.I. 13 at 13 (98 Civ. 1695)) Plaintiff alleges that some of these ADE reports did not even involve its generic warfarin sodium tablets. (D.I. 1, P 38 (98 Civ. 1695)) Plaintiff further claims that defendant solicited a large number of reports or reported events that the health care providers in question did not consider "adverse events;" indeed, many health care providers were unaware of being credited with ADE reports. (D.I. 1, PP 39, 41, 42 (98 Civ. 1695))

[*15]

The FDA admonished defendant for its assertions that additional blood testing was required following a switch from Coumadin to generic warfarin sodium. (D.I. 1, P 28 (98 Civ. 1695)) For instance, in objecting to defendant's slide presentation, the FDA stated:

> It is misleading to suggest that generic products that FDA has determined are bioequivalent to Coumadin, may not be therapeutically equivalent to the reference product without substantial evidence to support such a claim. All FDA approved dosage forms of generic drugs classified as therapeutically equivalent . . . can be substituted for the reference product with the full expectation that the substituted product will produce the same clinical effect and safety profile.

(D.I. 1, P 29 (98 Civ. 1695) (citing FDA letter of 8/26/97, at 2))

In addition to its anticompetitive communications, defendant allegedly entered into a variety of anticompetitive rebate, "market retention" agreements, and "inventory management" agreements with pharmacy benefit managers, retail pharmacies, and pharmaceutical wholesalers in order to preserve its monopoly in the oral anticoagulant market. (D.I. 1, PP 53-62 (98 Civ. 1695)) According **[*16]** to plaintiff, defendant offered and paid rebates to pharmacy benefit managers n9 to ensure the dispensing of Coumadin rather than plaintiff's generic warfarin sodium. (D.I. 1, P 54 (98 Civ. 1695)) It is alleged in this regard that defendant rewarded large pharmacy and drug store chains for stocking Coumadin as a substantial part of their oral anticoagulant inventory. (D.I. 1, P 56 (98 Civ. 1695)) The "inventory management" agreements offered wholesalers "unprecedented rebates" and "extended payment terms" for purchases of specific quantities of Coumadin during July, August, and September of 1997. (D.I. 1, P 59 (98 Civ. 1695)) Defendant allegedly timed these agreements to coincide with plaintiff's introduction of its generic warfarin sodium. (D.I. 1, P 60 (98 Civ. 1695)) Defendant has offered similar "inventory management" incentives covering purchases in 1998. (D.I. 1, PP 60, 62 (98 Civ. 1695)) Plaintiff argues that these agreements have had the net effect of excluding its generic warfarin sodium from the oral anticoagulant market. (D.I. 1, P 57 (98 Civ. 1695))

> n9 Pharmacy benefit managers dictate which brands of pharmaceuticals will be dispensed to patients of managed care organizations and insurance companies. According to plaintiff, "almost three-quarters of all the prescriptions dispensed in this country are affected by such third-party adjudication." (D.I. 1, P 54 (98 Civ. 1695))

[*17]

III. POST-TRANSFER APPLICABLE LAW

In the leading case on choice of law in multidistrict transfers, the District of Columbia Circuit Court has noted that "the law of a transferor forum on a federal question . . . merits close consideration, but does not have start decisis effect in a transferee forum situated in another circuit." *In re Korean Airlines Disaster, 265 U.S. App. D.C. 39, 829 F.2d 1171, 1176 (D.C. Cir. 1987),* aff'd on other grounds sub nom. *Chan v. Korean Airlines Ltd., 490 U.S. 122, 104 L. Ed. 2d 113, 109 S. Ct. 1676 (1989).* In *In re Donald J. Trump Casino Sec. Litig., 7 F.3d 357 (3d Cir. 1993),* the Third Circuit assumed, without deciding, that the district court's adoption of the District of Columbia Circuit's rationale was proper. See *id. at 367 n.8.* The Second Circuit also has held that a transferee federal court should apply its interpretations of federal law, not the transferor forum's constructions of federal law. See *Coker v. Pan Am. World Airways, Inc., 950 F.2d 839, 847 (2d Cir. 1991)* (concerning transfer motion pursuant to *28 U.S.C. § 157*(b)(5)).

Accordingly, the court will apply Third Circuit precedent to the federal questions **[*18]** presented by these consolidated cases. Where no Third Circuit precedent exists, the court will give careful consideration

to the law of the transferor forum. As for the state law issues presented in this case, the rule of *Van Dusen v. Barrack, 376 U.S. 612, 11 L. Ed. 2d 945, 84 S. Ct. 805 (1964)*, requires the court to apply the substantive state law of the jurisdiction in which the action was filed.

IV. STANDARD OF REVIEW

In analyzing a motion to dismiss pursuant to Rule 12(b)(6), the court must accept as true all material allegations of the complaint, and it must construe the complaint in favor of the plaintiff. See *Trump Hotels & Casino Resorts, Inc. v. Mirage Resorts, Inc., 140 F.3d 478, 483 (3d Cir. 1998)*. "A complaint should be dismissed only if, after accepting as true all of the facts alleged in the complaint, and drawing all reasonable inferences in the plaintiff's favor, no relief could be granted under any set of facts consistent with the allegations of the complaint." Id. Claims may be dismissed pursuant to a Rule 12(b)(6) motion only if the plaintiff cannot demonstrate any set of facts that would entitle it to relief. See *Conley v. Gibson, 355* **[*19]** *U.S. 41, 45-46, 2 L. Ed. 2d 80, 78 S. Ct. 99 (1957)*. The moving party has the burden of persuasion. See *Kehr Packages, Inc. v. Fidelcor, Inc., 926 F.2d 1406, 1409 (3d Cir. 1991)*. With these rules in mind, the court turns to an examination of the sufficiency of plaintiff's and class plaintiffs' complaints.

V. SUFFICIENCY OF PLAINTIFF'S COMPLAINT

Defendant argues that the court should dismiss plaintiff's monopolization and attempted monopolization claims. Further, defendant argues that its conduct does not state a claim under either the Lanham Act or under § 2(c) of the Robinson-Patman Act. Defendant also asserts that plaintiff has failed to allege the necessary elements of the state law business tort claims asserted against defendant. The court will address each of these issues in turn.

A. Plaintiff's Monopolization and Attempted Monopolization Claims

Section 2 of the Sherman Act punishes "every person who shall monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States." *15 U.S.C. § 2* ("Sherman § 2"). The offense of monopolization under § 2 of the Sherman Act requires proof **[*20]** of: "(1) possession of monopoly power in the relevant market; and (2) the willful acquisition or maintenance of that power, as distinguished from the growth or development as a consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell Corp., 384 U.S. 563, 570-71, 16 L. Ed. 2d 778, 86 S. Ct. 1698 (1966)*. In order to prevail on an attempted monopolization claim, a plaintiff must show "(1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power." *Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 456, 122 L. Ed. 2d 247, 113 S. Ct. 884 (1993)*.

Defendant does not dispute that it enjoys monopoly power in the market for oral anticoagulants. At issue is whether defendant's actions amount to predatory conduct or the willful acquisition of monopoly power. Defendant argues that its petitions to federal and state legislatures and administrative bodies, as well as its statements to health care providers and the general public, do not constitute predatory conduct because they enjoy immunity from antitrust liability under the Noerr-Pennington **[*21]** doctrine. Defendant also claims that such activity is not "exclusionary" under Sherman § 2.

1. The Noerr-Pennington Doctrine

In *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 5 L. Ed. 2d 464, 81 S. Ct. 523 (1961)*, the Supreme Court held that concerted efforts to restrain or monopolize trade by petitioning the government enjoy antitrust immunity. See also *United Mine Workers v. Pennington, 381 U.S. 657, 670, 14 L. Ed. 2d 626, 85 S. Ct. 1585 (1965)* (holding that "joint efforts to influence public officials do not violate the antitrust laws even though intended to eliminate competition."). The Court has broadened Noerr-Pennington immunity to include the petitioning of the executive and judicial branches of government. n10 See *California Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 513, 30 L. Ed. 2d 642, 92 S. Ct. 609 (1972)*. The Supreme Court generally has refused to impose antitrust liability for petitioning the government because doing so would infringe upon the First Amendment's protection of free speech, chill public involvement in our representative government, and impermissibly extend the Sherman Act to cover **[*22]** political as well as commercial activity. See *Noerr, 365 U.S. at 137-38;* see also 10 Earl W. Kintner & Joseph P. Bauer, Federal Antitrust Law § 77.1, at 187-88 (1994).

n10 The Supreme Court has extended Noerr-Pennington immunity as well to the petitioning of nongovernmental bodies when they perform quasi-public duties. See *Allied Tube & Conduit Corp. v. Indian Head, Inc., 486 U.S. 492, 100 L. Ed. 2d 497, 108 S. Ct. 1931 (1988)*. The USP is a private entity, but it publishes the official compendium of pharmaceuticals in the United States. (D.I. 1, P 24 (98 Civ. 1695)) Since the USP promulgates standards governing

pharmaceuticals (through procedures similar to those used by administrative agencies), the court will analyze the defendant's petition to the USP as it would a petition before an administrative agency.

The Supreme Court has ruled, however, that frivolous and illegitimate petitioning of government bodies does not enjoy Noerr-Pennington immunity. In *City of Columbia v. Omni Outdoor* **[*23]** *Advertising, Inc., 499 U.S. 365, 113 L. Ed. 2d 382, 111 S. Ct. 1344 (1991),* the Court held that the "sham exception" to Noerr-Pennington immunity applies when "persons use the governmental process -- as opposed to the outcome of that process -- as an anticompetitive weapon." *Id. at 380.* The Court has enunciated a two-part test to identify sham proceedings. See *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 123 L. Ed. 2d 611, 113 S. Ct. 1920 (1993)* ("PRE").

The first prong of the test requires a court to determine n11 if the suit or proceeding is "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." *Id. at 60.* A suit is not objectively baseless if "an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome." Id. An antitrust plaintiff cannot prove a sham "merely by showing that its competitor's 'purposes were to delay [the plaintiff's] entry into the market.'" *Id. at 59-60* (quoting *Omni Outdoor, 499 U.S. at 381 (1991)).*

n11 Plaintiff argues the "baselessness" inquiry is inherently a question of fact and, therefore, inappropriate for resolution by the court. (D.I. 13 at 15 (98 Civ. 1695)) The Supreme Court, however, has found that a court may decide, as a matter of law, whether a party invoking Noerr-Pennington immunity had probable cause to bring an allegedly baseless suit. See *PRE, 508 U.S. at 63.* A finding of probable cause "compels the conclusion that a reasonable litigant in the defendant's position could realistically expect success on the merits of the challenged lawsuit." Id.

[*24]

Only if challenged litigation is "baseless" may courts examine the subjective motivations of the litigant. The second prong of the test invites courts to determine whether a defendant has anticompetitive motivations. Specifically, this second prong instructs courts to "focus on whether the baseless lawsuit conceals 'an attempt to interfere directly with the business relationships of a competitor.'" *PRE, 508 U.S. at 60-61* (quoting *Noerr, 365 U.S. at 144)).*

a. Defendant's Petition for Stay to the FDA

Plaintiff alleges that defendant's petition to the FDA was baseless in that it lacked expert testimony and evidentiary support. In support of its position, plaintiff quotes the former head of the FDA's Office of Generic Drugs as stating that defendant's Petition for Stay was "in the class of an economic challenge" rather than a scientific one. (D.I. 1, P 23 (98 Civ. 1695)) Plaintiff complains that defendant's "maneuverings before the FDA delayed the introduction of [its] product by several months and imposed substantial additional costs on [it] and loss of sales revenue." (D.I. 1, P 23 (98 Civ. 1695))

Other than conclusory allegations that defendant's petition lacked **[*25]** evidentiary support, plaintiff offers no basis for its assertion that defendant initiated its Petition for Stay without any "realistic expectation of success on the merits." *PRE, 508 U.S. at 60.* The complaint reveals that defendant's Petition for Stay proposed more stringent bioequivalency standards governing generic substitutes for Coumadin, but does not allege that defendant included fraudulent or misleading information in its Petition for Stay.

Without more, plaintiff cannot show that defendant's Petition for Stay lacked "a realistic expectation of success on the merits." See *PRE, 508 U.S. at 60.* Indeed, the complaint suggests that an objective litigant could conclude that defendant's Petition for Stay was "reasonably calculated to elicit a favorable outcome." Id. The complaint reveals that defendant petitioned the FDA for adoption of narrower bioequivalency standards -- standards that the FDA had the exclusive power to set. In its ten page reply to the Petition for Stay, the FDA did not find the petition frivolous or unreasonable. Indeed, the FDA granted defendant's request that ANDA applicants be required to conduct certain tests unrelated to bioequivalency. Moreover, **[*26]** the FDA later proposed to adopt the very bioequivalency standards recommended by defendant in its Petition for Stay. See *62 Fed. Reg. 67880, 67881* (Dec. 17, 1997).

The Supreme Court has recognized that "a successful 'effort to influence government action . . . certainly cannot be characterized as a sham.'" *PRE, 508 U.S. at 58* (quoting *Allied Tube, 486 U.S. at 502).* Plaintiff has failed to provide a basis for inferring that defendant's Petition for Stay was anything other than a successful attempt to secure more stringent bioequivalency standards for generic warfarin sodium drugs. Defendant's motion to dismiss plaintiff's antitrust

claim, as the claim relates to the Petition for Stay, is granted.

b. Defendant's Petition to the USP

Likewise, plaintiff's complaint is devoid of any facts from which the court could infer that defendant's USP petition lacked a "realistic expectation of success on the merits." *PRE, 508 U.S. at 60.* Plaintiff's complaint reveals only that defendant's petition requested a specific form of relief uniquely within the competence of the USP. Plaintiff presents no evidence that would support an inference of frivolousness or baselessness. **[*27]** Although the USP denied defendant's petition, the "court must resist the understandable temptation to engage in post hoc reasoning by concluding that an ultimately unsuccessful action must have been unreasonable or without foundation." *PRE, 508 U.S. at 61 n.5* (internal quotations and citations omitted). Defendant's motion to dismiss plaintiff's antitrust claim, insofar as it is based on defendant's petition to the USP, is granted.

2. Defendant's Alleged Abuse of the FDA's ADE Reporting System

Plaintiff alleges that defendant submitted fraudulent ADE reports to the FDA and used these ADE reports in administrative hearings before state agencies. (D.I. 1, PP 38, 46 (98 Civ. 1695)) Defendant argues that these ADE reports, even if fraudulent, also enjoy Noerr-Pennington immunity. The Supreme Court, however, has declined to extend Noerr-Pennington immunity to deceptive practices before adjudicatory bodies like administrative agencies or courts. In California Motor Transport, the Court noted that "misrepresentations, condoned in the political arena, are not immunized when used in the adjudicatory process." *California Motor Transp., 404 U.S. at 513;* see also **[*28]** *Allied Tube, 486 U.S. at 500* (remarking that "in less political arenas, unethical and deceptive practices can constitute abuses of administrative or judicial processes that may result in antitrust violations"). Administrative agencies, like state pharmacy boards, act in an adjudicatory capacity when they consider petitions urging the adoption of stricter standards governing NTI drugs.

Accepting the facts contained in the complaint as true, the court can infer that defendant used fraudulent and misleading ADE reports before state administrative agencies. Supplying fraudulent information to state agencies "threatens the fair and impartial functioning of [such] agencies and does not deserve immunity from the antitrust laws." *Clipper Exxpress v. Rocky Mountain Motor Tariff Bureau, Inc., 690 F.2d 1240, 1261 (9th Cir. 1982).* Insofar as plaintiff's Sherman § 2 claim rests on defendant's use of fraudulent ADE reports before state agencies, defendant's motion to dismiss is denied.

Plaintiff's complaint also alleges that defendant used the ADE reports to urge state legislators to exclude generic warfarin sodium from state generic substitution laws. False statements made to legislators **[*29]** and legislative bodies in an effort to change government policy are protected by Noerr-Pennington immunity. In Noerr, the Court noted that deception in the political arena, "reprehensible as it is, can be of no consequence so far as the Sherman Act is concerned." *Noerr, 365 U.S. at 145.* False statements in the political arena enjoy antitrust immunity because "there is an emphasis on debate in the political sphere, which can accommodate false statements and reveal their falsity." *Clipper Exxpress, 690 F.2d at 1261.* Consequently, plaintiff may not rest its monopolization claims on defendant's misrepresentations to state legislators or legislative bodies. n12

n12 Plaintiff argues that the "commercial exception" to Noerr-Pennington immunity subjects defendant to antitrust liability for its misrepresentations to state legislatures that purchased pharmaceuticals for its citizens. Because neither the Second nor the Third Circuits have recognized the existence of this exception to Noerr-Pennington immunity and because the court has denied defendant's motion to dismiss on other grounds, the court declines to address the validity of plaintiff's "commercial exception" theory.

[*30]

3. Defendant's Statements to the General Public and the Health Care Industry

Defendant argues that its statements to the general public and to the health care industry, even if false and misleading, are protected by the Noerr-Pennington doctrine because they were made as part of a campaign "to shape public policy regarding patient safety in the use of NTI drugs." (D.I. 12 at 10 (98 Civ. 1695)) Alternatively, defendant argues that its "statements of opinion" do not give rise to antitrust liability because they are not exclusionary conduct.

a. Noerr-Pennington Immunity

The Supreme Court has held that, where an anticompetitive restraint arises solely from private action, "the restraint cannot form the basis for antitrust liability if it is 'incidental' to a valid effort to influence government action." *Allied Tube, 486 U.S. at 499* (citing *Noerr, 365 U.S. at 143)* (emphasis added)); see also *Massachusetts School of Law, Andover v. American Bar Ass'n, 107 F.3d 1026, 1035 (3d Cir. 1997)* ("MSL"). The

Supreme Court has recognized, however, that "the validity of such efforts, and thus the applicability of Noerr immunity, varies with the context and [*31] nature of the activity." *Allied Tube, 486 U.S. at 499.*

The question at bar is whether defendant's public statements were incidental to valid efforts to persuade government agencies to adopt more stringent bioequivalency standards for generic warfarin sodium drugs. Defendant argues that its public statements were "part and parcel" of its campaign to influence public officials and its statements, even if false and misleading, enjoy Noerr-Pennington immunity. (See D.I. 12 at 10 (98 Civ. 1695))

Defendant's attempts to influence public officials centered on the establishment of stricter bioequivalency standards. In contrast, defendant's public statements warned consumers of "medical-legal" exposure in switching from Coumadin to generic warfarin sodium and urged doctors to conduct additional blood tests following a switch to generic warfarin sodium. (See D.I. 1, PP 18, 34 (98 Civ. 1695)) Defendant impugned the quality of plaintiff's generic warfarin sodium and issued press releases publicizing allegedly false ADE reports related to generic warfarin sodium. (See D.I. 1, PP 31, 46 (98 Civ. 1695))

In Noerr, where the railroads published false and misleading public [*32] statements about the trucking industry, those statements were directly related to the railroads' efforts to obtain legislation regarding truck weight limits and increased taxes on heavy trucks. The railroads' publicity campaign addressed the damage done to highways by overweight trucks, the failure of the trucking industry to pay its fair share of road maintenance costs, and the hazards created by overweight trucks. See *Noerr, 365 U.S. at 131.* Indeed, the Supreme Court held that **"at least insofar as the railroads's [publicity] campaign was directed toward obtaining governmental action,** its legality was not at all affected by any anticompetitive purpose it may have had." *Id. at 139-40* (emphasis added). In the case at bar, the court cannot infer at this stage of the proceedings that the totality of defendant's public statements were "part and parcel" of its efforts to secure more stringent bioequivalency standards for warfarin sodium drugs. For purposes of this motion to dismiss, therefore, the court finds that defendant's statements to the general public and to the health care community do not warrant Noerr-Pennington immunity.

b. Sherman § 2

Defendant cites [*33] MSL for the proposition that the Third Circuit has refused to construe false and misleading speech as exclusionary activity under Sherman § 2. In MSL, the Massachusetts School of Law argued that it was injured by the stigmatic effect of the ABA's refusal to accredit it. See *MSL, 107 F.3d at 1037-38.* It claimed this stigmatic effect arose from the ABA's attempts to convince states to make graduation from an ABA accredited law school necessary for bar admission. The law school characterized the ABA's efforts as a "campaign to convey the idea that ABA accreditation is the sine qua non of quality." *Id. at 1037.* In affirming the district court's granting of summary judgment in favor of the ABA, the court found that the complained-of speech amounted to nothing more than "the ABA's justification of its accreditation decisions." Id.

Unlike the facts in MSL, where the ABA was found merely to have defended its own standard setting and accreditation decisions, defendant's speech at issue is directed at consumers and directly attacks the quality and substitutability of plaintiff's generic warfarin sodium. The court finds the Third Circuit's decision in MSL inapposite [*34] under these circumstances.

Other courts have recognized that misleading advertising can rise to the level of anticompetitive conduct if the plaintiff "overcome[s] a presumption that the effect on competition of such a practice was de minimis." *Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 288 n.41 (2d Cir. 1979)*(quoted in *National Ass'n of Pharm. Mfrs., Inc. v. Ayerst Labs., 850 F.2d 904, 916 (2d Cir. 1988)).* The Second Circuit, in a case factually similar to the one at bar, held that a plaintiff may overcome the de minimis bar (and a motion to dismiss) by "cumulative proof that [defendant's] representations were (1) clearly false, (2) clearly material, (3) clearly likely to induce reasonable reliance, (4) made to buyers without knowledge of the subject matter, (5) continued for prolonged periods, and (6) not readily susceptible of neutralization or other offset by rivals." *Ayerst Labs., 850 F.2d at 916.* In the absence of Third Circuit precedent, the court finds these factors helpful in determining whether defendant's allegedly false and misleading statements rise to the level of unlawful exclusionary conduct.

In the present case, plaintiff's complaint [*35] satisfies each of the above six factors. The complaint alleges that defendant's extensive publicity campaign contained false misrepresentations. Plaintiff claims that these material misrepresentations were made to the general public in order to induce potential consumers to avoid purchasing generic warfarin sodium. On a motion to dismiss, plaintiff is entitled to the inference that the general public lacked the sophistication to discern that defendant's statements about bioequivalency were false. Although defendant argues that its statements were "readily susceptible to neutralization" by plaintiff and the FDA (D.I. 14 at 19-20) (98 Civ. 1695)), defendant is not entitled to this inference on a motion to dismiss.

Moreover, plaintiff's dismal market share belies this assertion. (See D.I. 1, P 16 (98 Civ. 1695)).

Consequently, the court finds that defendant's allegedly false and misleading speech had more than a de minimis effect on competition. Plaintiff may premise its Sherman § 2 claim on defendant's public statements.

4. Defendant's Rebate and Market Retention Agreements

Plaintiff claims that defendant's various rebate and market retention agreements also violate **[*36]** § 2 of the Sherman Act. Plaintiff argues that these agreements, in combination with defendant's misleading statements, have had the "synergistic effect" of harming competition in the oral anticoagulant market. (D.I. 13 at 27-29 (98 Civ. 1695)) Defendant contends that its price discounts and its allegedly deceptive statements "cannot possibly be viewed as working together 'synergistically' to produce an anticompetitive result because the theories of competitive harm are fundamentally at odds with each other." (D.I. 14 at 21 (98 Civ. 1695))

In analyzing an antitrust complaint, the court recognizes that "plaintiffs should be given the full benefit of their proof without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each." *Continental Ore Co. v. Union Carbide & Carbon Corp., 370 U.S. 690, 699, 8 L. Ed. 2d 777, 82 S. Ct. 1404 (1962)*. The court finds that the combined effect of defendant's conduct could harm competition in the oral anticoagulant market. Those consumers that defendant failed to scare away from generic warfarin sodium could be "bought off" by defendant's rebate and inventory management incentives. Thus, defendant's **[*37]** allegedly misleading statements, coupled with financial disincentives to purchase generic warfarin sodium, could form part of an unlawful, multifaceted effort to hinder competition in the oral anticoagulant market.

In sum, plaintiff may premise its Sherman § 2 claim on defendant's use of allegedly fraudulent ADE reports before state agencies, defendant's allegedly false and misleading statements to the general public and the health care community, and defendant's use of rebates and market retention agreements as part of its allegedly multifaceted effort to restrain trade in the oral anticoagulant market. Plaintiff may not base its Sherman § 2 claim on defendant's petitions to the FDA or USP or defendant's use of allegedly fraudulent ADE reports before state legislatures.

B. Plaintiff's Lanham Act Claim

Plaintiff claims that defendant violated § 43(a) of the Lanham Act by misrepresenting the nature, characteristics, and quality of plaintiff's product to "the public at large, wholesalers, pharmacies and health care professionals, as well as state and federal regulators." (D.I. 1, P 73 (98 Civ. 1695)) The Lanham Act imposes civil liability on those who, "**in commercial advertising [*38] or promotion**, misrepresent[] the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services or commercial activities. . . ." *15 U.S.C. § 1125*(a)(1)(B) (emphasis added). The Act protects "consumers and competitors from a myriad of misrepresentations of products and services in commerce." *Wojnarowicz v. American Family Ass'n, 745 F. Supp. 130, 141 (S.D.N.Y. 1990)* (quoting *Allen v. National Video, Inc., 610 F. Supp. 612, 625 (S.D.N.Y. 1985))*.

Defendant contends that its public statements are immune from Lanham Act liability because they were not made in the context of "commercial advertising or promotion." Alternatively, defendant argues that, even if its statements occurred in the context of commercial advertising or promotion, its commercial speech was "inextricably intertwined" with protected First Amendment speech designed to influence public policies regarding warfarin sodium drugs. The court must determine whether defendant's public statements occurred "in commercial advertising or promotion" and, if so, whether those statements enjoy First Amendment protection from Lanham Act liability.

1. "In Commercial Advertising [*39] or Promotion"

There is a dearth of case law addressing whether a defendant's communications occurred "in commercial advertising or promotion." This is so because "generally, a plaintiff can easily satisfy its burden of proving that the complained-of representation was made in 'commercial advertising or promotion' by pointing to paid advertisements by a commercial defendant on television or radio, or in newspapers or magazines." *Gordon & Breach Science Publishers S.A. v. American Inst. of Physics, 859 F. Supp. 1521, 1532 (S.D.N.Y. 1994)*. Here, defendant's allegedly false and misleading statements did not appear in the classic form of an advertising campaign. Instead, they were made in the context of press releases, computer software, letters, and facsimile transmissions.

Courts that have addressed the "commercial advertising or promotion" issue have concluded that "the [Lanham] Act's reach is broader than the 'classic advertising campaign.'" *Seven-Up Co. v. Coca-Cola Co., 86 F.3d 1379, 1384 (5th Cir. 1996)* (quoting *Gordon & Breach, 859 F. Supp. at 1534 (S.D.N.Y. 1994))*. Courts, for instance, have found § 43(a) applicable to the fundraising letters of a nonprofit **[*40]** pregnancy counseling group, see *Birthright v. Birthright, Inc., 827*

F. Supp. 1114, 1137-38 (D.N.J. 1993), and to an individual's "bad-mouthing" of her former company in telephone calls to friends and former colleagues, see *National Artists Management Co. v. Weaving, 769 F. Supp. 1224, 1234-35 (S.D.N.Y. 1991).*

The district court in Gordon & Breach, after an extensive analysis of case law and legislative history, distilled four factors necessary to satisfy the "commercial advertising or promotion" requirement of § 43(a)(1)(B). The statements must be

> (1) commercial speech; (2) by a defendant who is in commercial competition with plaintiff; (3) for the purpose of influencing consumers to buy defendant's goods or services . . . (4) . . . disseminated sufficiently to the relevant purchasing public to constitute "advertising" or "promotion" within that industry.

Gordon & Breach, 859 F. Supp. at 1535-36; accord *Seven-Up Co., 86 F.3d at 1384* (finding the district court's analysis "accurate and sound").

Applying this analysis to the facts at bar, defendant's statements satisfy at least three Gordon & Breach factors. Defendant competes with plaintiff **[*41]** in the oral anticoagulant market. Plaintiff sufficiently alleges that defendant's statements influenced doctors, pharmacists, and others to purchase or prescribe Coumadin instead of generic warfarin sodium. Defendant disseminated its statements to such a wide audience of the healthcare industry that plaintiff is entitled to the inference that defendant engaged in advertising or promotion. (See, e.g., D.I. 1 at P (alleging that defendant faxed a misleading letter to 45,000 pharmacists))

Turning to the final factor, the "commercial speech" requirement, the Supreme Court has defined "commercial speech" as "speech proposing a commercial transaction." *United States v. Edge Broad. Co., 509 U.S. 418, 426, 125 L. Ed. 2d 345, 113 S. Ct. 2696 (1993);* see also *Board of Trustees of State Univ. of N.Y. v. Fox, 492 U.S. 469, 473-74, 106 L. Ed. 2d 388, 109 S. Ct. 3028 (1989)* (characterizing the proposal of a commercial transaction as "**the test** for identifying commercial speech") (emphasis added). n13 Defendant contends that none of its statements proposed any commercial transactions; rather, its statements conveyed merely "that care should be taken in switching between warfarin **[*42]** products given warfarin sodium's status as an NTI drug." (D.I. 14 at 24) A review of plaintiff's complaint indicates that not all of defendant's statements are subject to such an innocuous interpretation.

> n13 Defendant's petitions to the FDA, the USP, and those state agencies that merely set standards governing the bioequivalency of generic drugs do not fall within this definition. Plaintiff has not alleged, nor could it, that any statements made to these regulatory bodies proposed a commercial transaction.

For instance, defendant's "Couma Care" computer software included praise for the "high quality" of Coumadin while warning of the "risks" and "medical-legal exposure" entailed in switching from Coumadin to generic warfarin sodium. (D.I. 1, P 18 (98 Civ. 1695)) In a press release coinciding with the introduction of plaintiff's warfarin sodium tablets, defendant claimed that "while [plaintiff] focuses on producing a cheaper product to help save money, [defendant] focuses on patient safety and education and **[*43]** the future health of over two million patients who depend on Coumadin everyday." (D.I. 1, P 31 (98 Civ. 1695)) Defendant also allegedly employed false ADE reports to dissuade pharmacists and state pharmacy boards from purchasing plaintiff's generic warfarin sodium.

Statements such as these satisfy the court that defendant's press releases and other communications were not confined solely to defendant's efforts to influence public policy on generic substitution of warfarin sodium drugs. Plaintiff at this stage of the proceedings is entitled to the inference that defendant's statements "proposed a commercial transaction" by (1) denigrating plaintiff's generic warfarin sodium, (2) stressing the dangers of substituting generic warfarin sodium for Coumadin, and (3) touting Coumadin's "high quality" and "tighter than USP" content uniformity specifications. (See D.I. 1, PP (98 Civ. 1695))

In order to state a prima facie case under § 43(a) of the Lanham Act, the Third Circuit has ruled that a plaintiff must show

> 1) that the defendant has made false or misleading statements as to his own product [or another's]; 2) that there is actual deception or at least a tendency to **[*44]** deceive a substantial portion of the intended audience; 3) that the deception is material in that it is likely to influence purchasing decisions; 4) that the advertised goods travelled in interstate

> commerce; and 5) that there is a likelihood of injury to the plaintiff in terms of declining sales, loss of goodwill, etc.

U.S. Healthcare, Inc. v. Blue Cross of Greater Phila., 898 F.2d 914, 922-23 (3d Cir. 1990) (quoting *Max Daetwyler Corp. v. Input Graphics, Inc., 545 F. Supp. 165, 171 (E.D. Pa. 1982)).* Consistent with its findings above, the court finds that plaintiff has satisfied each element of its prima facie case.

Nonetheless, the court still must determine whether defendant's commercial speech enjoys First Amendment protection. Defendant contends that its statements are "inextricably intertwined" with protected political speech and, consequently, all of its communications are entitled to full First Amendment protection. Defendant relies heavily on the Supreme Court's decision in *Riley v. National Federation of the Blind, 487 U.S. 781, 101 L. Ed. 2d 669, 108 S. Ct. 2667 (1988).* In Riley, the Court assessed the constitutionality of a North Carolina statute **[*45]** which required solicitors of charitable contributions to divulge to potential donors the percentage of the previous year's donations that actually went to charities. In deciding that it would apply strict scrutiny analysis to the statute, the Court noted that "where, as here, the component parts of a single speech are inextricably intertwined, we cannot parcel out the speech, applying one [standard of review] test to one phrase and another test to another phrase." *Id. at 796.*

The Court revisited the issue of "inextricably intertwined" speech in Fox. See *492 U.S. 469, 109 S. Ct. 3028, 106 L. Ed. 2d 388.* In Fox, the Court reviewed the constitutionality of a state university regulation that prohibited private commercial enterprises in student dormitory rooms. The Court distinguished its holding in Riley by finding that the essentially commercial "Tupperware parties" involved in Fox did not enjoy full First Amendment immunity from state regulation -- even though the commercial activity at issue in Fox combined "sales pitches" with lectures on home economics, personal finance, and other protected forms of "pure" speech. Writing for the Court, Justice Scalia explained that in Riley,

> the **[*46]** commercial speech (if it was that) was "inextricably intertwined" because the state law required that it be included. By contrast, there is nothing whatever "inextricable" about the noncommercial aspects of these ["Tupperware"] presentations. No law of man or of nature makes it impossible to sell housewares without teaching home economics, or to teach home economics without selling housewares.

Fox, 492 U.S. at 474.

Defendant fails to appreciate the Supreme Court's distinction between the protected "inextricably intertwined" speech in Riley and the unprotected "voluntarily intertwined" speech in Fox. In the case at bar, defendant voluntarily interspersed its protected speech relating to heightened standards for warfarin sodium drugs with comments about plaintiff's product, which comments are alleged to be false and misleading. Nothing required defendant to mislead consumers and disparage plaintiff's product while expressing its protected opinions on the standards governing warfarin sodium.

Thus, defendant's commercial speech is not "inextricably intertwined" with its protected speech. Because false and misleading commercial speech does not enjoy First Amendment **[*47]** protection, n14 defendant's statements are subject to Lanham Act scrutiny. Defendant's motion to dismiss plaintiff's Lanham Act claim is denied.

> n14 Commercial speech, when found to be false and misleading, "is not protected by the First Amendment at all." *City of Cincinnati v. Discovery Network, Inc., 507 U.S. 410, 434, 123 L. Ed. 2d 99, 113 S. Ct. 1505* (Blackmun, J., concurring). Commercial speech enjoys "less protection . . . than . . . other constitutionally safeguarded forms of expression", *Bolger v. Youngs Drug Prods. Corp., 463 U.S. 60, 64-65, 77 L. Ed. 2d 469, 103 S. Ct. 2875 (1983),* because "there is greater potential for deception or confusion in the context of certain advertising messages." *Id. at 65.* Moreover, commercial speech is marked by "greater objectivity and hardiness . . . [which] may make it less necessary to tolerate inaccurate statements for fear of silencing the speaker." *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 771 n.24, 48 L. Ed. 2d 346, 96 S. Ct. 1817 (1976).*

[*48]

C. Plaintiff's Robinson-Patman Claim

Section 2(c) of the Robinson-Patman Act reads, in relevant part:

> It shall be unlawful for any person engaged in commerce, in the course of such commerce, to pay or grant . . . anything of value as a commission, brokerage, or other compensation, or any allowance or discount in lieu thereof, except for services rendered in connection with the sale or purchase of goods . . . either to the other party to such transaction or to an agent, representative, or other intermediary therein where such intermediary is acting in fact for or in behalf, or is subject to the direct or indirect control, of any party to such transaction other than the person by whom such compensation is so granted or paid.

15 U.S.C. § 13(c). Congress enacted this section in order to combat the use of "dummy" brokerage fees as a means of securing unlawful price rebates. The Supreme Court has found the language of § 2(c) applicable to commercial bribery. See *FTC v. Henry Broch & Co., 363 U.S. 166, 169 n.6, 4 L. Ed. 2d 1124, 80 S. Ct. 1158 (1960)* ("the debates on the bill show clearly that § 2(c) was intended to proscribe other practices such as the 'bribing' **[*49]** of a seller's broker by the buyer") (dictum). Commercial bribery is an aspect of "the classic arrangement that § 2(c) aimed to eliminate -- a situation where the fiduciary of one party is influenced by another party to the transaction by the payment of brokerage when no services are performed." *Yeager's Fuel, Inc. v. Pennsylvania Power & Light Co., 953 F. Supp. 617, 665 (E.D. Pa. 1997);* accord *Harris v. Duty Free Shoppers Ltd., 940 F.2d 1272, 1274 & n.3 (9th Cir. 1991).* With respect to commercial bribery, the Third Circuit has required the plaintiff to show that "the illegal payments in question crossed the line from buyer to seller or vice versa." See *Environmental Tectonics v. W.S. Kirkpatrick, Inc., 847 F.2d 1052, 1066 (3d Cir. 1988)* (citing *Seaboard Supply Co. v. Congoleum Corp., 770 F.2d 367, 372 (3d Cir. 1985)).*

Defendant argues that plaintiff has failed to allege that the financial incentives offered by defendant constituted unlawful bribes to fiduciaries of Coumadin purchasers. (D.I. 12, at 25-26 (98 Civ. 1695)) In its complaint, plaintiff alleges that defendant paid rebates and/or "administrative fees" to pharmacy benefit managers, managed care companies, **[*50]** retail pharmacies, and pharmacy wholesalers. (D.I. 1, PP 53, 56, 57, 59 (98 Civ. 1695)) Plaintiff explains that pharmacy benefit managers act as fiduciaries for managed care companies, insurance companies, and others who employ them to broker cost-effective deals with pharmaceutical sellers. Plaintiff claims that these rebates and fees were designed to exclude its generic warfarin sodium from the anticoagulant market. (D.I. 1, at P 53 (98 Civ. 1695)) Plaintiff further alleges that these payments were not made in exchange for any services rendered in connection with the sale of Coumadin. (D.I. 1, PP 53, 58 (98 Civ. 1695))

At this stage of the proceedings plaintiff's complaint permits the inference that defendant unlawfully bribed these pharmacy benefit managers as well as the ultimate purchasers of Coumadin. Because these rebates were never offered by defendant until the introduction of generic warfarin sodium (D.I. 1, P 61 (98 Civ. 1695)), the court can also infer that these financial incentives were offered in order to exclude generic warfarin sodium from the oral anticoagulant market. As such, plaintiff has stated a claim of commercial bribery under § 2(c) of the Robinson-Patman **[*51]** Act.

D. Plaintiff's New York General Business Law Claims

Count V of the complaint alleges that defendant's false and misleading statements violated § § 349 and 350 of the New York General Business Law. Section 349 prohibits "deceptive acts or practices in the conduct of any business, trade or commerce." *N.Y. Gen. Bus. L. § 349* (McKinney 1997). Section 350 states that "false advertising in the conduct of any business, trade or commerce or in the furnishing of any service in this state is hereby declared unlawful." Id. § 350. In an action brought under either section, the plaintiff must show "(i) that the act or practice was misleading in a material respect, and (ii) that the plaintiff was injured." *Coors Brewing Co. v. Anheuser-Busch Cos., 802 F. Supp. 965, 975 (S.D.N.Y. 1992).* Although the New York legislature enacted the statute as a consumer protection measure, see *Genesco Entertainment v. Koch, 593 F. Supp. 743, 751 (S.D.N.Y. 1984),* "corporate competitors now have standing to bring a claim under this [statute] . . . so long as some harm to the public at large is at issue." *Bristol-Myers Squibb Co. v. McNeill-P.P.C., Inc., 786 F. Supp. 182, 215* (E.D.N.Y.), **[*52]** vacated in part on other grounds, *973 F.2d 1033 (2d Cir. 1992).* "The critical question, then, is whether the matter affects the public interest in New York, not whether the suit is brought by a consumer or a competitor." *Securitron Magnalock Corp. v. Schnabolk, 65 F.3d 256, 264 (2d Cir. 1995).*

In its supporting brief, defendant reiterates its claim that its public statements enjoy First Amendment immunity and, therefore, cannot serve as grounds for liability under the New York General Business Law. (D.I. 12 at 28 n.9 (98 Civ. 1695)) Consistent with the findings above that at least some of defendant's speech is not protected by the First Amendment, the court further finds that plaintiff has alleged materially false and

misleading statements by the defendant that harmed purchasers of anticoagulant drugs. Therefore, the plaintiff has stated a claim for relief under § § 349 and 350 of the New York General Business Law. Defendant's motion to dismiss these claims is denied.

E. Plaintiff's New York Common Law Claims

In Count VI of its complaint, plaintiff alleges that defendant's false statements constituted common law trade disparagement. "Trade libel or product disparagement [*53] is an action to recover for words or conduct which tend to disparage or negatively reflect upon the condition, value or quality of a product or property." *Angio-Medical Corp. v. Eli Lilly & Co., 720 F. Supp. 269, 274 (S.D.N.Y. 1989).* In order to prove product disparagement the plaintiff must plead and prove "(1) falsity of the statement, (2) publication to a third person, (3) malice (express or implied), and (4) proven special damages." Id. New York courts have defined special damages as "the pecuniary loss resulting directly from the effect of a defendant's allegedly wrongful conduct." *Charles Atlas, Ltd. v. Time-Life Books, Inc., 570 F. Supp. 150, 155 (S.D.N.Y. 1983);* see also *Angio-Medical Corp., 720 F. Supp. at 274* (describing special damages as the "natural and immediate consequence of the disparaging statements"). Loss of sales is a proper item of special damages. See *Charles Atlas, Ltd., 570 F. Supp. at 155.*

In the case at bar, plaintiff sufficiently alleges that defendant's numerous public comments were malicious and that they disparaged the quality of plaintiff's generic warfarin sodium. Defendant argues that plaintiff has failed to properly plead special [*54] damages because plaintiff has not specified the particular customers with whom it would have done business but for defendant's disparaging statements. While defendant rightly notes that some New York courts have required such specificity, at least one New York court has recognized the need for a more liberal approach in cases where it is "virtually impossible to identify those who did not order the plaintiff's product" because "such people would simply have failed to order, thus leaving no record of their identity." *Charles Atlas, Ltd., 570 F. Supp. at 156* (citing William Prosser, Handbook of the Law of Torts § 128, at 921-22 (4th ed. 1971); see also *Teilhaber Mfg. Co. v. Unarco Materials Storage, 791 P.2d 1164, 1167 (Colo. Ct. App. 1989).*

Plaintiff has not cited the specific customers it lost because of defendant's allegedly false and misleading statements. Plaintiff, however, has alleged that its market share in the oral anticoagulant market has suffered because of defendant's allegedly misleading publicity campaign. At this stage of the proceedings, the court finds that plaintiff has pled special damages with sufficient particularity. Given the mass dissemination of [*55] defendant's allegedly false and misleading statements, the court finds that demanding more specificity from plaintiff at this early stage in the litigation would be unfair and inappropriate.

Count VII of plaintiff's complaint alleges tortious interference with prospective business relations. In order to prevail on such a claim, "a plaintiff must demonstrate that the defendant interfered with business relations existing between a plaintiff and a third party, either with the purpose of harming the plaintiff or by means that are dishonest, unfair, or improper." *Volvo N. Am. Corp. v. Men's Int'l Prof'l Tennis Council, 857 F.2d 55, 74 (2d Cir. 1988).* A cause of action for tortious interference with prospective business advantage "applies to those situations where the third party would have entered into or extended a contractual relationship with plaintiff but for the intentional and wrongful acts of the defendant." *M.J. & K. Co. v. Matthew Bender & Co., 220 A.D.2d 488, 631 N.Y.S.2d 938, 940 (N.Y. App. Div. 1995)* (quoting *WFB Telecomms., Inc. v. NYNEX Corp., 188 A.D.2d 257, 590 N.Y.S.2d 460, 461 (N.Y. App. Div. 1992)).*

In the present case, plaintiff alleges that, due to defendant's [*56] false and misleading statements, pharmacy benefit managers, managed care companies, and others refused to purchase plaintiff's generic warfarin. The facts reveal that these entities normally prefer less expensive generic drugs to branded pharmaceuticals. At this stage of the proceedings, plaintiff is entitled to the inference that, but for defendant's false and misleading statements, these third parties would have entered into contracts with plaintiff. Plaintiff has presented sufficient factual support to state a claim for relief under common law tortious interference with prospective business advantage. Defendant's motion to dismiss is denied.

VI. SUFFICIENCY OF CLASS PLAINTIFFS' COMPLAINTS

Class plaintiffs' antitrust complaints are identical: they seek treble damages and injunctive relief under § § 4 and 16 of the Clayton Act for allegedly supracompetitive prices charged for Coumadin by defendant. Class plaintiffs' factual summaries of defendant's alleged violations of Sherman § 2 mirror plaintiff's complaint. The court will address class plaintiffs' antitrust claims as a whole. Class plaintiff Tischler also alleges that defendant's actions violate the Florida Deceptive [*57] and Unfair Trade Practices Act ("DUTPA"). *Fla. Stat. Ann. § § 501.201* et seq. Class plaintiff Steckel additionally alleges several Pennsylvania state law claims.

A. Class Plaintiffs Lack Antitrust Standing

Class plaintiffs seek treble damages under § 4 of the Clayton Act n15 for the allegedly supracompetitive prices charged for Coumadin by defendant. Citing the Supreme Court's decision in *Illinois Brick Co. v. Illinois, 431 U.S. 720, 52 L. Ed. 2d 707, 97 S. Ct. 2061 (1977),* defendant argues that class plaintiffs lack antitrust standing because they are indirect purchasers of Coumadin. Class plaintiffs argue that the "bright-line" rule of Illinois Brick does not bar their claim because the Supreme Court has enunciated a broader antitrust standing test in *Associated General Contractors, Inc. v. California State Council of Carpenters, 459 U.S. 519, 74 L. Ed. 2d 723, 103 S. Ct. 897 (1983)* ("AGC"). The court finds that even under the more flexible balancing test of AGC, class plaintiffs still lack antitrust standing.

n15 Section 4 of the Clayton Act provides, in pertinent part, that "any person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws may sue therefor in any district court . . . and shall recover threefold the damages by him sustained. . . ." *15 U.S.C. § 15*(a).

[*58]

In AGC, the Supreme Court synthesized its previous rulings on antitrust standing by analyzing five factors to resolve the standing issue before it. As the Third Circuit explained in *McCarthy v. Recordex Serv., Inc., 80 F.3d 842, 850 (3d Cir. 1996),* the Supreme Court considered (1) the causal connection between the antitrust violation and the harm to the plaintiff, (2) whether the antitrust injury is "of the type that the antitrust statute was intended to forestall," (3) the directness or indirectness of the asserted injury, (4) the existence of more direct victims of the alleged violation, and (5) the potential for duplicative recovery or complex apportionment of damages. See *id. at 850* (citing *AGC, 459 U.S. at 537-44).*

These factors, when applied to the facts at bar, weigh heavily against class plaintiffs. Factors one and three require class plaintiffs to show that defendant's monopolization of the oral anticoagulant market directly caused their injuries. Although class plaintiffs assert that they were forced to pay supracompetitive prices, their ability to trace this effect to the alleged anticompetitive conduct traverses "several somewhat vaguely defined links." **[*59]** *AGC, 459 U.S. at 540.*

In their complaints, class plaintiffs assert that class members may be identified from records maintained by pharmacies, drugstores, and managed care companies. (D.I. 1, P 7 (C.A. 97-659)) This demonstrates that class plaintiffs purchased Coumadin from intermediaries rather than from defendant. Each of these organizations purchased their supplies of Coumadin from pharmaceutical wholesalers. (D.I. 8 at 11 (C.A. 97-659)) Class plaintiffs, then, are third in the distribution chain of Coumadin. Although class plaintiffs do not discuss third party payor arrangements, it is almost certain that most of the 1.8 million class members had some sort of health insurance. More often than not, third party payors actually "pay" for the cost of prescriptions while patients pay only a yearly premium (some of which might be subsidized by the patient's employer). Other third party payor arrangements reimburse patients for part or all of the price paid for the prescription.

In sum, this case presents a classic indirect purchaser scenario. It is unclear from the complaints whether class plaintiffs suffered any antitrust injury at all. Any injuries actually suffered by class **[*60]** plaintiffs are too remote to justify antitrust standing.

Turning to the fourth AGC factor, the remoteness of class plaintiffs' injuries also points to the existence of more direct victims of defendant's allegedly unlawful conduct. If defendant's monopolization of the oral anticoagulant market resulted in supracompetitive prices for Coumadin, the insurance companies and third party payor organizations most likely absorbed some or all of that overcharge. Those organizations, and not more remote victims like class plaintiffs, are the proper parties to bring suit to recover the overcharge.

The fifth factor of the AGC analysis concerns the potential for duplicative recovery or complex apportionment of damages. Allowing class plaintiffs to proceed in the present case would expose defendant to multiple recoveries in antitrust actions brought by those more directly injured by its conduct. Moreover, the sheer variety of third party payor plans would render the apportionment of damages among the class plaintiffs incredibly complex. A trier of fact would have to ascertain the percentage of the overcharge actually suffered by each class plaintiff. This figure would vary from plaintiff **[*61]** to plaintiff due to the involvement of third party payors and other intermediary purchasers -- some of which may or may not have absorbed the alleged overcharge. The apportionment problem is magnified by the fact that class plaintiffs purport to represent 1.8 million consumers of Coumadin.

The court concludes that class plaintiffs have not adequately alleged antitrust injury. As the Supreme Court has recognized, "an antitrust violation may be expected to cause ripples of harm to flow through the Nation's economy; but 'despite the broad wording of § 4 there is a point beyond which the wrongdoer should not

be held liable.'" *Blue Shield of Va. v. McCready, 457 U.S. 465, 476-77, 73 L. Ed. 2d 149, 102 S. Ct. 2540 (1982)* (citing *Illinois Brick, 431 U.S. at 760* (Brennan, J., dissenting)). Class plaintiffs at bar lack antitrust standing, and defendant's motion to dismiss their Sherman § 2 claims is granted.

B. Injunctive Relief

Class plaintiffs seek injunctive relief from defendant's alleged monopolistic practices under § 16 of the Clayton Act. Section 16 provides, in relevant part, that "any person . . . shall be entitled to sue for and have injunctive relief . . . against **[*62]** threatened loss or damage by a violation of the antitrust laws. . . ." *15 U.S.C. § 26*. The Supreme Court has held that "in order to seek injunctive relief under § 16, a private plaintiff must allege threatened loss or damage 'of the type the antitrust laws were designed to prevent and that flows from that which makes defendant['s] acts unlawful.'" *Cargill, Inc. v. Monfort of Colo., Inc., 479 U.S. 104, 113, 93 L. Ed. 2d 427, 107 S. Ct. 484 (1986)* (citing *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489, 50 L. Ed. 2d 701, 97 S. Ct. 690 (1977))*. The Court remarked in Cargill that it would be "anomalous . . . to read the Clayton Act to authorize a private plaintiff to secure an injunction against a threatened injury for which he would not be entitled to compensation if the injury actually occurred." *479 U.S. at 112*. See also *West Penn Power Co., 147 F.3d at 264* (holding that "when seeking injunctive relief [under the Clayton Act], 'the complainant need only demonstrate a significant threat of injury from an impending violation of the antitrust laws.'") (emphasis added & citation omitted).

In the present case, class plaintiffs have not sufficiently alleged **[*63]** either antitrust injury or a causal connection between defendant's allegedly unlawful activity and their purported injury. Thus, class plaintiffs have failed to allege injury of the type the Sherman Act was designed to prevent. Therefore, class plaintiffs do not have standing to assert injunctive relief under § 16 of the Clayton Act.

C. Class Plaintiffs' State Law Claims

Because the court has dismissed class plaintiffs' federal claims, the only claims remaining arise out of state statutes and state common law. Pursuant to *28 U.S.C. § 1367*(c)(2)-(3), the court declines to exercise supplemental jurisdiction over these state claims because state law issues substantially predominate over the now dismissed federal claims. Therefore, the court grants defendant's motions to dismiss class plaintiffs' complaints.

VII. CONCLUSION

For the reasons stated, defendant's motion to dismiss plaintiff's claims is granted in part and denied in part. Defendant's motions to dismiss class plaintiffs' claims are granted. An order shall issue consistent with this memorandum opinion.

E

LEXSEE 1996 U.S. DIST. LEXIS 22567

ZENITH LABORATORIES, INC., Plaintiff, v. ABBOTT LABORATORIES, Defendant.

Civil Action No. 96-1661

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

1996 U.S. Dist. LEXIS 22567

August 5, 1996, Decided
August 7, 1996, Filed

NOTICE: [*1] NOT FOR PUBLICATION

DISPOSITION: Defendant's motion to dismiss denied and plaintiff's motion for partial summary judgment denied.

LexisNexis(R) Headnotes

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JUDGES: JOHN W. BISSELL, United States District Judge.

OPINIONBY: JOHN W. BISSELL

OPINION: BISSELL, District Judge

This matter comes before the Court on a motion to dismiss and a motion for partial summary judgment. On April 15, 1996, plaintiff Zenith Laboratories, Inc. filed the instant complaint against defendant Abbott Laboratories. The complaint charges the defendant with unfair competition, abuse of process, [*2] tortious interference and fraud. It also seeks a declaratory judgment that plaintiff is not infringing defendant's relevant patents.

This Court has jurisdiction pursuant to *28 U.S.C. § 1331*.

FACTS AND BACKGROUND

The pharmaceutical industry is regulated by the Food and Drug Administration ("FDA"). The Federal Food, Drug and Cosmetic Act ("FFDCA") is the statute addressed to the manufacture and distribution of drugs and medical devices. See *21 U.S.C. § 301*, et seq. New drug products, methods for employing those products and variations of the original drug may all receive individual patents. Once a drug is patented, it must receive FDA approval before it may be marketed in the United States. (Id.) The FFDCA sets out the specific requirements for obtaining marketing approval by the FDA. (Id.) However, in 1984, the FFDCA was amended by the Drug Price Competition and Patent Term Restoration Act, otherwise known as the "Hatch-Waxman Act," which modifies the necessary approval procedures. (Codified as amended at *21 U.S.C. § 355* (1994) and *35 U.S.C. § 271*(d)-(h) (1995)). [*3]

The Hatch-Waxman Act provides for an abbreviated approval process for generic forms of previously approved pioneer drug products whose patents have or

will soon expire or are proven invalid. A pharmaceutical company seeking approval to market a generic product must complete an Abbreviated New Drug Application ("ANDA"). The generic producer is excused from conducting the extensive clinical tests required for a New Drug Application ("NDA"). The ANDA applicant may rely upon the pioneer company's tests. It need only prove that the generic contains the same active ingredient as, and is bioequivalent to, the patented drug.

Another significant difference made by the Hatch-Waxman Act is that the generic applicant may now use the patented drug to perform certain research and development without infringing the patent of the pioneer manufacturer. Prior to the amendment, the FFDCA provided:

> Whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent.

Accordingly, prior to the Hatch-Waxman Act, a producer of a generic product was required to wait until the pioneer drug went off patent **[*4]** before that producer could conduct the research and development necessary for FDA approval of a generic product. As a result, the patent owner was entitled to a de facto extension of the term of the patent, the duration of which was equivalent to the time the generic producer needed to research its proposed product and obtain FDA approval. The FFDCA now reads:

> It shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs . . . .

35 U.S.C. § 271(e)(1). This provision is widely known as the "safe harbor" provision in that it permits otherwise infringing activity as long as it is reasonably related to obtaining regulatory approval for the generic drug product.

In the event the generic producer wishes to seek FDA approval during the term of the pioneer patent, the generic applicant must address each patent that claims the pioneer drug by including one of the following four certifications in its application:

> 1. that the pioneer has not filed patent information **[*5]** with the FDA,
>
> 2. that the patent has expired.
>
> 3. that the patent expires on a date before which the generic manufacturer is seeking to market its infringing equivalent, or
>
> 4. that the patent claiming the marketed pioneer drug is invalid or will not be infringed.

21 U.S.C. § 355(j)(2)(vii). If the generic applicant makes the fourth certification, it must provide notice of the certification to the patent owner and explain why the patent is invalid or will not be infringed. *21 U.S.C. § 355*(j)(2)(B). The Hatch-Waxman Act permits the patent owner to file a patent infringement action within 45 days of receipt of such notice. Prior to the Hatch-Waxman Act, preapproval patent infringement litigation was not available to the patent owner. The Act provides that infringement occurs if a generic manufacturer submits:

> an application under section 505(j) of the Federal Food, Drug and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent.

35 U.S.C. § 271(e)(2). Such a suit delays the approval of the generic product **[*6]** up to 30 months or until a judicial resolution of the infringement issues, whichever comes first. *21 U.S.C. § 355*(j)(4)(B)(iii). Once a "paragraph IV" certification is made and an infringement action filed, the issues of the validity and accuracy of the patent are resolved by the court, not the FDA.

The Hatch-Waxman Act benefits only those patent owners whose patents have been approved by the FDA for marketing. For approval, a patent owner is required to:

> file with the FDA the patent number and expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

21 U.S.C. § 355(b)(1). Once this information is received and the patent approved, it is published in a volume known as "Approved Drug Products With Therapeutic Equivalence Evaluations," which is commonly referred to as the "Orange Book." A patent is properly listed in the Orange Book if it claims an FDA-

approved [*7] drug product and is a patent with respect to which a claim of infringement could reasonably be asserted. Zenith argues that Abbott has improperly listed patents in the Orange Book by purporting that these patents claim the drug which is the subject of a pioneer patent with the purpose of invoking the Hatch-Waxman Act in order to keep Zenith out of the relevant market for up to 30 months and to subject it to sham patent infringement litigation.

Abbott discovered and patented terazosin hydrochloride, which is used for the treatment of hypertension and benign prostatic hyperplasia. The '894 patent covers the compound itself and the '097 patent covers a specific composition and the method for treating hypertension with terazosin hydrochloride. Both of these patents have expired. The '532 patent covers a dihydrate form of terazosin hydrochloride, which is marketed by Abbott as "Hytrin." The '532 patent expires in May 1998. At the time they were issued, the above patents were listed in the FDA Orange Book. Other patents issued to Abbott, which Abbott claims are covered by the '532 patent, include the '176 patent, the '617 patent, the '095 patent and the '207 patent. These patents are all [*8] for anhydrous polymorphs of terazosin hydrochloride and differ from Hytrin only in their specific crystalline forms. They are all bioequivalent to Hytrin. These patents were listed in the Orange Book in 1994 and 1995.

Zenith intends to market a polymorph of terazosin hydrochloride, which is bioequivalent to "Hytrin." Zenith claims that its product has a different crystalline structure and therefore does not infringe the patent on Hytrin. On or about August 1, 1994, Zenith filed an ANDA with the FDA seeking permission to market its generic version of an anhydrous form of terazosin hydrochloride. At the time, Zenith made the required certifications, including one with respect to the '894 patent, which had expired, one with respect to the '097 patent which would expire prior to the date Zenith sought approval, and one with respect to the '532 patent, alleging that Zenith's product would not infringe that patent. Abbott did not file a patent infringement suit in response.

However, Abbott contends that Zenith's product infringes not the '532 patent, but its '615 patent which covers an anhydrous polymorph of terazosin hydrochloride. In 1994, Abbott filed a patent infringement suit, pursuant [*9] to the Hatch-Waxman Act, asserting that Zenith was infringing the '615 patent. At the time, the '615 patent was not listed in the FDA Orange Book and the suit was therefore dismissed for failure to state a claim. Shortly thereafter, Abbott listed the '615 patent in the Orange Book, claiming that it covered Hytrin, the subject of Abbott's '532 patent, and refiled its complaint. However, that action was also dismissed, this time on the grounds that the listing was untimely. The issue of whether the '615 patent was improperly listed or infringed has not yet been addressed.

In its complaint, Zenith contends that Abbott's listing of the '615, '176, '095 and '207 patents was improper. Specifically, Zenith argues that none of these patents are covered by Hytrin, an approved drug product, as they claim. Because the listing of a patent entitles a patent owner to the protections of the Hatch-Waxman Act, Zenith claims that Abbott, knowing the relevant patents are not covered by Hytrin, had them listed anyway for the purpose of forcing Zenith to make a paragraph IV certification, which then entitles Abbott to have delayed FDA approval of Zenith's generic product for up to 30 months by instituting [*10] a patent infringement suit against Zenith. The complaint asserts counts of unfair competition, abuse of process, tortious interference and fraud. It also seeks a declaration that its generic product does not infringe any of Abbott's patents.

ANALYSIS

I. Abbott's Motion to Dismiss is Denied

A. Standard for a Motion to Dismiss

Fed. R. Civ. P. 12(b)(6) authorizes a court to dismiss a claim on the basis of a dispositive issue of law. *Neitzke v. Williams, 490 U.S. 319, 326, 104 L. Ed. 2d 338, 109 S. Ct. 1827 (1989)* (citing *Hishon v. King & Spalding, 467 U.S. 69, 73, 81 L. Ed. 2d 59, 104 S. Ct. 2229 (1984); Conley v. Gibson, 355 U.S. 41, 45-46, 2 L. Ed. 2d 80, 78 S. Ct. 99 (1957)*. In disposing of a motion to dismiss, the court operates on the assumption that the factual allegations in the complaint or counterclaim are true. *Neitzke, 490 U.S. at 326-27*. A motion to dismiss may be granted if the opposing party would not be entitled to relief under any set of facts consistent with the allegations in the complaint or counterclaim. As the Supreme Court stated in Neitzke:

> nothing in [*11] Rule 12(b)(6) confines its sweep to claims of law which are obviously insupportable. On the contrary, if as a matter of law "it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations," *Hishon, supra at 73, 104 S. Ct. 2229,* a claim must be dismissed, without regard to whether it is based on an outlandish legal theory or on a close but ultimately unavailing one. What Rule 23(b)(6) does not countenance are

> dismissals based on a judge's disbelief of a complaint's factual allegations.

(490 U.S. at 327).

B. Zenith's Claims Arising Under State Law are not Preempted by the FFDCA.

Zenith's complaint charges Abbott with state law claims of unfair competition, abuse of process, tortious interference with prospective economic advantage and fraud. It also seeks a declaration of noninfringement. The conduct from which these claims arose is the alleged improper listing of Abbott's patents in the FDA Orange Book which, as Zenith claims, precipitated sham patent infringement litigation. Abbott contends these claims are preempted by the FFDCA and moves to dismiss the action.

Certain claims are expressly **[*12]** preempted by the FFDCA. However, the parties agree that the state law claims at issue are not among those expressly preempted. In the absence of an express statutory provision, state law is preempted only when the state law "actually conflicts with federal law" or "federal law so thoroughly occupies a legislative field as to make reasonable the inference that Congress left no room for the States to supplement it." *Cipollone v. Liggett Group, Inc., 505 U.S. 504, 523, 120 L. Ed. 2d 407, 112 S. Ct. 2608 (1992).*

As an initial matter, it is persuasive that Congress expressly preempted state law claims pertaining to the safety of medical devices but did not expressly preempt any other claims. *21 U.S.C. § 360k*(a). Such limited preemption leads to a reasonable inference that Congress intended to preempt only those claims specifically enumerated within the statute and for those not listed to remain viable. *Cipollone, 505 U.S. at 517.*

That the FFDCA is a comprehensive piece of legislation does not imply that it entirely occupies the regulated field.

> Preemption does not follow immediately from the comprehensive federal regulation **[*13]** of prescription biological products. Every subject that merits congressional legislation is, by definition, a subject of national concern. That cannot mean, however, that every federal statute ousts all related state law.

Abbot by Abbot v. American Cyanamid, 844 F.2d 1108, 1112 (4th Cir. 1988). Furthermore, the state laws that regulate competition in the marketplace and the FFDCA are not in conflict and easily coexist. The goal of the FFDCA is the protection of public health. Common law claims such as those asserted here address wrongful business practices. It simply cannot be said that such state laws "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Freightliner Corp. v. Myrick, 514 U.S. 280, 115 S. Ct. 1483, 1487, 131 L. Ed. 2d 385 (1995).* In addition, state claims of unfair competition and the like provide a remedy for conduct not addressed by the FFDCA which is the alleged improper listing of patents with the FDA.

Numerous courts considering the issue of preemption of those state laws that regulate the conduct of competitors in the marketplace have found that **[*14]** state law claims similar to those asserted in the underlying complaint are not preempted. *Michael v. Shiley, Inc., 46 F.3d 1316, 1329 (3d Cir. 1995)* (common law fraud claim asserted against a competitor not preempted); *Spychala v. G.D. Searle & Co., 705 F. Supp. 1024, 1029 (D.N.J. 1988)* (claims involving medical devices preempted, claims involving prescription drugs not preempted); *Hawkins v. Upjohn Co., 890 F. Supp. 609, 612 (E.D. Tex. 1994)* (fraud "and other general torts" not preempted by the FFDCA). Furthermore, a violation of the FFDCA that gives rise to a separate cause of action does not necessarily lead to the conclusion that such a claim is preempted. *Reese v. Payless Drug Stores Northwest, Inc., 34 Cal. App. 4th 19, 40 Cal. Rptr. 2d 75 (Ct. App. 1995)* (unfair competition not preempted). State law claims that do not hinge upon the validity or infringement of a patent are not preempted. *Cover v. Hydramatic Packing Co., 83 F.3d 1390 (Fed. Cir. 1996).* The instant state law claims involve the question of whether the defendant has attempted to invoke the provisions of the Hatch-Waxman Act to gain **[*15]** an unfair competitive advantage. For the reasons stated above, this Court concludes that the FFDCA does not preempt plaintiff's state law claims relating to alleged unlawful business practices.

C. Zenith's State Law claims are Sufficient to Withstand a 12(b)(6) Motion.

It must be remembered that on a motion to dismiss the complaint, "the plaintiff is afforded the safeguard of having all its allegations taken as true and all inferences favorable to plaintiff will be drawn." *Westinghouse Elec. Corp. v. Franklin, 789 F. Supp. 1313, 1317 (D.N.J. 1992)* rev'd on other grounds, *993 F.2d 349 (3d Cir. 1993).* A claim of unfair competition is one directed toward an entity that does not play fair, one who disparages or wrongfully captures the trade of another. *American Shops, Inc. v. American Fashion Shops of*

Journal Square, Inc., 13 N.J. Super. 416, 420-21, 80 A.2d 575 (App. Div. 1951). Unfair competition encompasses an actionable infringement of a property right, "i.e., the right to pursue one's business, calling or occupation free from undue interference or molestation." *Kamm v. Flink, 113 N.J.L. 582, 586, 175 A. 62* [*16] (E. & A. 1934).

In Count One, Zenith claims that Abbott has unfairly and unlawfully sought to obstruct competition in the market for terazosin hydrochloride by causing allegedly improper listings in the FDA Orange Book and instituting sham litigations against Zenith. New Jersey law provides:

> If a competitor . . . engages in fraud . . . or misrepresents, or threatens civil . . . actions, or violates the law, then the competition is considered to be outside of permissible parameters, and liability will ensue.

C.R. Bard v. Wordtronics Corp., 235 N.J. Super. 168, 174, 561 A.2d 694 (Law Div. 1989). Assuming the allegations in the complaint are true and considering that federal law does not preempt this claim, this Court determines that Zenith has articulated a claim of unfair competition against Abbott. n1 However, whether Zenith will ultimately prevail on such a claim is, at this time, far from clear.

> n1 This Court notes that Abbott's contention that the claim of unfair competition should be dismissed on the grounds that Zenith has not suffered any injury is unfounded. In the event that Abbott's conduct is ultimately determined to constitute unfair competition, Zenith has already had to defend against two "bogus" lawsuits for patent infringement. That money damages are not yet quantifiable is irrelevant.

[*17]

2. Abuse of Process

In Count Two, Zenith claims that the two prior lawsuits initiated by Abbott for patent infringement were improper and therefore an abuse of process. To prevail on a claim for abuse of process, the plaintiff must demonstrate an existence of an ulterior motive or purpose and some act in the use of legal process not proper in the regular prosecution of the proceedings. *Harris Custom Builders, Inc. v. Hoffmeyer, 834 F. Supp. 256, 263 (N.D. Ill. 1993).* Zenith claims that Abbott has filed patent infringement actions against it, knowing that those actions were meritless and with the purpose of attempting to keep Zenith out of the terazosin hydrochloride market for 30 months when Abbott knew it was not entitled to such an extension on its exclusive position in the pharmaceutical industry. Like Zenith's claim for unfair competition, the claim for abuse of process claim is sufficiently stated to withstand a motion to dismiss.

3. Tortious Interference with Prospective Economic Advantage

Count Three charges Abbott with tortious interference with Zenith's prospective economic advantage. The claimed economic advantage is that which Zenith expected [*18] to gain from the approval and marketing of its generic product. To prevail on such a claim, Zenith must establish that it had a reasonable expectation of economic benefit and that the defendant knowingly interfered with a benefit that had a reasonable likelihood of accruing to the plaintiff. *Fineman v. Armstrong World Indus., Inc., 980 F.2d 171, 186 (3d Cir. 1992).* The complaint charges Abbott with the knowledge that its '615 patent was improperly listed and the meritless pursuit of a patent infringement action with the purpose of keeping Zenith out of the terazosin hydrochloride market. Had Abbott's patent not been improperly listed, assuming for the instant purposes that it was, Zenith's generic product had a reasonable likelihood of approval without the statutory 30 month waiting period. Accordingly, Zenith has stated a claim for tortious interference with prospective economic advantage.

4. Fraud

Count Four charges Abbott with common law fraud. In order to state such a claim, plaintiff must allege: (1) defendant made a material factual misrepresentation to plaintiff; (2) with the knowledge or belief of its falsity; (3) with the intention that plaintiff rely [*19] upon the representation; and (4) that plaintiff justifiably relied upon the misrepresentation to its detriment. *Agathos v. Starlite Motel, 977 F.2d 1500, 1508 (3d Cir. 1992).* The fraud alleged to have occurred is Abbott's representation that it would use the samples of Zenith's generic product submitted to it by Zenith for the sole purpose of characterizing and identifying the terazosin hydrochloride in the generic product. (Letter dated Sept. 15, 1994, Exh. A). Zenith argues that Abbott received the samples, knowing the product could not infringe its '532 patent, with the intent of using those samples for the separate purpose of subjecting the compound to x-ray diffraction tests, which purpose was vastly beyond the scope of what was necessary to determine whether the '532 patent was infringed. (Letter dated Sept. 22, 1994).

Even if these promises of Abbott are considered half-truths, New Jersey courts hold:

> A half-truth may be as misleading as a statement which is wholly false. A fraudulent misrepresentation may inhere in a statement which is truthful so far as it goes but which is materially misleading because of the failure to recite qualifying matters. **[*20]** The intentional concealment of material information is tantamount to an affirmative misrepresentation of the nonexistence of such information.

Medivox Productions, Inc. v. Hoffmann-LaRoche, Inc., 107 N.J. Super. 47, 69-70, 256 A.2d 803 (Law Div. 1969). Accordingly, this Court concludes that Zenith has adequately alleged a claim of common law fraud.

C. Zenith has Adequately Pled a Claim for a Declaratory Judgment.

Zenith's fifth count seeks a declaratory judgment that its generic form of terazosin hydrochloride does not infringe any of Abbott's relevant terazosin hydrochloride patents. Zenith also seeks a declaration that the '615, '176, '095 and '207 patents are improperly listed in the FDA Orange Book in that none of those patents are covered by Abbott's Hytrin product and an order requiring Abbott to delist those patents.

For this Court to assert jurisdiction over Zenith's declaratory judgment claim, Zenith must have a reasonable apprehension of suit and have made meaningful preparation to commit acts Abbott would likely contest as infringing of its patents. *DuPont Merck Pharmaceutical v. Bristol-Myers Squibb, 62 F.3d 1397, 1401 (Fed.Cir. 1995).* **[*21]** Both elements are satisfied. Zenith is in a position to begin marketing immediately its generic product after FDA approval. In addition, Abbott has twice filed patent infringement suits against Zenith with respect to its generic of terazosin hydrochloride and has also filed similar suits against other potential marketers of terazosin hydrochloride. (Rocco Del., PP 3, 8, 14). This history of litigation regarding alleged infringement of Abbott's terazosin hydrochloride patents is a clear indication that, should Zenith seek approval of its generic product and make a "paragraph IV" certification that Abbott's patent is invalid, Zenith will be sued by Abbott for patent infringement, which suit would delay the marketing of the generic product for up to 30 months. *DuPont, 62 F.3d at 1400-1401* (holding the fear of an infringement suit in response to a "paragraph IV" certification was within that required to establish jurisdiction over a claim for a declaratory judgment); *Infinitech, Inc. v. Vitrophage, Inc., 842 F. Supp. 332, 337-38 (N.D. Ill. 1994)* (public interest in the development and marketing of new medical products favors the adjudication of a declaratory **[*22]** judgment action prior to the expiration of a patent in the event the patent may be invalid and undeserving of a full term). As Zenith has demonstrated that a controversy exists and that a declaratory judgment of noninfringement would not conflict with the purposes of the statutory system, this Court concludes that it has jurisdiction over Zenith's claim for a declaratory judgment. This Court also concludes that, having met the requirements for a declaratory judgment, plaintiff has satisfied the necessary jurisdictional showing regardless of the fact that the FFDCA does not expressly provide for a private right of action. it is not an action under the FFDCA plaintiff seeks to pursue but under the Declaratory Judgment and All Writs Acts and state law. n2

> n2 In fact, the Northern District of Illinois, in considering other listings of Abbott in the FDA Orange Book, entertained a request for a declaratory judgment and, having found those listings to be improper, ordered Abbott to remove those listed patents from the Orange Book. *Abbott Lab. v. Geneva Pharms., 1996 U.S. Dist. LEXIS 9762,* Civ. No. 95 C 6657 (N.D. Ill. Apr. 9, 1996) (Mentlik Decl., Exh. 20).

[*23]

II. Zenith's Motion for Partial Summary Judgment is Denied.

A. Standard for a Motion for Summary Judgment

Federal Rule of Civil Procedure 56(c) provides that summary judgment should be granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Fed. R. Civ. P. 56(c)*; see also *Chipollini v. Spencer Gifts, Inc., 814 F.2d 893, 896* (3d Cir.) (en banc), cert. dismissed, *483 U.S. 1052 (1987).* In deciding a motion for summary judgment, a court must view the facts in the light most favorable to the nonmoving party and must resolve any reasonable doubt as to the existence of a genuine issue of fact against the moving party. *Continental Insurance Co. v. Bodie, 682 F.2d 436, 438 (3d Cir. 1982).* The moving party has the burden of establishing that there exists no genuine issue of material fact. See *Celotex Corp. v. Catrett, 477 U.S. 317, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (1986).*

The Supreme Court has stated **[*24]** that, in applying the criteria for granting summary judgment,

> the judge must ask . . . not whether . . . the evidence unmistakably favors one side or the other but whether a fair-minded jury could return a verdict for the [nonmoving party] on the evidence presented. The mere existence of a scintilla of evidence in support of the [non-movant's] position will be insufficient; there must be evidence on which the jury could reasonably find for the [nonmoving party]. The judge's inquiry, therefore, unavoidably asks whether reasonable jurors could find by a preponderance of the evidence that the [non-movant] is entitled to a verdict. . . .

Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986). A fact is "material" only if it will affect the outcome of a lawsuit under the applicable law, and a dispute over a material fact is "genuine" if the evidence is such that a reasonable fact finder could return a verdict for the nonmoving party. (Id.)

In order to survive a motion for summary judgment, an opposing party must present "more than a mere scintilla of evidence" in his favor. He "cannot simply reallege factually **[*25]** unsupported allegations contained in his pleadings." *Anderson v. Liberty Lobby, 477 U.S. 242, 251, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986);* see also *Maguire v. Hughes Aircraft Corp., 912 F.2d 67, 72 (3d Cir. 1990).* Only evidence that would be admissible at trial may be used to test a summary judgment motion. Evidence with a deficient foundation must be excluded from consideration. *Williams v. Borough of West Chester, PA, 891 F.2d 458, 466 (3d Cir. 1989);* see also *Trap Rock Indus., Inc. v. Local 825, Int'l Union of Operating Eng'rs, 982 F.2d 884, 890-91 (3d Cir. 1992).*

B. The Instant Case

Zenith moves for summary judgment on the issue of whether the listing of Abbott's '176, '615, '095 and '207 patents was improper, In the event this Court were to make such a finding, Zenith asks for the entry of an order directing Abbott to delist those patents. Zenith argues that those patents are improperly listed because, although they claim Hytrin, none of them is actually covered by the Hytrin patent. Abbott disputes this and contends that its patents are covered by Hytrin. As Hytrin covers a dihydrate form of terazosin **[*26]** hydrochloride and the subsequent patents were issued for different anhydrous polymorphs of terazosin hydrochloride, which for the FDA's purposes are allegedly the same, Abbott submits that the contested patents properly claim Hytrin and that the listing of those patents in the FDA Orange Book was correct.

Title *21 U.S.C. § 355* sets out the requirements for the listing of drug patents in the FDA Orange Book:

> The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

21 U.S.C. § 335(b)(1). The following regulation has been implemented by the FDA to facilitate compliance with § 355:

> For patents that claim a drug substance or a drug product, the applicant shall submit information only on those patents that claim a drug product that is the subject of a pending or approved application, **[*27]** or that claim a drug substance that is a component of such a product.

21 C.F.R. § 314.53(b). A listed drug is that which is also defined as approved for safety and effectiveness under § 355(c). *21 U.S.C. § § 355*(j)(2)(A) and (6)(A)(ii). Accordingly, the FDA approves for listing only those patents covered by an approved drug product. Therefore, if Abbott's patents are covered by Hytrin, which is an approved drug product, listing is appropriate.

As an initial matter, the FDA approved Abbott's '176, '615, '095 and '207 patents for listing. Such approval demonstrates that the FDA believed that those patents are covered by an approved drug product. The drug product that the FDA agreed covered the contested patents is, as those patents claim and Abbott submits, Hytrin. Both parties cite Pfizer, Inc. v. FDA in support of their arguments. *753 F. Supp. 171 (D. Md. 1990).* In Pfizer, the FDA refused to list a patent that failed to claim an approved drug product. Specifically, Pfizer had an approved patent which claimed nifedipine solution in an oral release capsule. It then sought to have approved a patent on a tablet formulation of nifedipine. **[*28]** As the tablet patent did not claim the FDA-approved oral release capsule, the FDA refused to approve the tablet formulation of nifedipine. n3 However, the patents at

issue in the instant case do not claim an unapproved drug product, they claim the FDA-approved drug product of Hytrin.

n3 Although not discussed in the papers, it would seem that the purpose behind the requirement that a patent for which approval is sought must claim an approved drug product is that it allows the FDA to rely on the testing results of the previously-approved drug product in approving the patent that is the subject of the second application. In other words, if a patent for which approval is sought claims an approved drug product, the later patent may be approved on a more expedited basis because the FDA can rely on the tests performed on the previously-approved patent. This is essential because, where the later patent claims an approved drug product, it is considered the bioequivalent of that product. If a patent for which approval is sought fails to claim an approved drug product, it would likely be required to submit to lengthy and stringent safety and efficacy tests.

[*29]

Zenith argues that, although the FDA found that the patents are covered by Hytrin, which must be undisputed as the FDA approved and listed each of the contested patents, this does not necessarily mean that the patents are actually covered by, or claim, Hytrin. n4 Hytrin and the four patents at issue all have different crystalline formulations. As such, Zenith contends that one anhydrous polymorph is not covered by a different anhydrous polymorph. If this argument is correct, one anhydrous polymorph would not be covered by a different yet FDA-approved, anhydrous polymorph, and could therefore not be listed without its own safety and efficacy testing.

n4 The FDA admits that it does not have the resources to examine whether a patent is properly listed after listing takes place. If a listing is contested, the FDA requires the patent owner to certify that the listing is appropriate or to voluntarily cause the patent to be delisted. *21 C.F.R. § 314.53(f)*. Unless the patent owner changes the information submitted to the FDA, the FDA will not amend the Orange Book listing. (Id.) Abbott has certified that the listings are valid and refuses to delist its patents.

[*30]

The crux of this motion for partial summary judgment on the issue of improperly listed patents is what a subsequent patent must claim to be appropriate for listing. Must the patent claim only an approved drug product or must it claim both the approved drug product and, in the case of an anhydrous polymorph, its exact crystalline structure. Abbott argues that, because Hytrin, a dihydrate form of terazosin hydrochloride, is the drug product covered in the relevant patent, the subsequent patents need only claim the drug substance claimed in Hytrin. As the relevant patents were issued with respect to anhydrous polymorph of Hytrin, which differ only in crystalline structure, Abbott submits that they are covered by Hytrin.

The C.F.R. provides:

> For patents that claim a drug substance or a drug product, the applicant shall submit information only on those patents that claim a drug product that is the subject of an . . . approved application, or that claim a drug substance that is a component of such a product.

21 C.F.R. § 314.53(b). This Court reads this section to mean that if a patent claims the drug substance, or active ingredient, of an approved drug product, **[*31]** that patent is covered by the approved drug product and may be approved for marketing by the FDA and listed in the Orange Book.

The issue then becomes what is the relevant drug substance claimed by Hytrin and do the later Abbott patents claim that substance so that listing would be appropriate. Zenith argues that the relevant drug substance is the specific dihydrate form of terazosin hydrochloride, which is an anhydrous polymorph of terazosin hydrochloride. It argues that other crystalline forms of terazosin hydrochloride Abbott has patented do not claim the specific polymorph found in Hytrin. However, Abbott contends that the relevant drug substance is a general hydrated form of terazosin hydrochloride, and not the specific dihydrate formulation of that drug. In other words, Abbott argues that any patent on an anhydrous polymorph is covered by Hytrin as Hytrin claims a hydrated form, of the active ingredient and not the chemical make-up of that formulation.

The FDA provides that "anhydrous and hydrated entities are considered pharmaceutical equivalents." (Orange Book at xii, Coleman Decl., Exh. B). Pharmaceutical equivalents contain the same active ingredient. (Id., at vii). **[*32]** They differ in "shape, scoring configuration, packaging, excipients (including colors, flavors, preservatives), expiration time, and, within certain limits, labeling." (Id.) The FDA has

indicated that, as a general matter, "different polymorphic forms of the same drug substance (are the same) drug substances unless the differences in physical structure found in the polymorphs result in inequivalent safety and efficacy profiles." (FDA Response to Citizen Petition of Janssen Pharmaceuticals, Coleman Decl., Exh. C at 4). The FDA also considers "differences in waters of hydration resulting in polymorphic crystal forms of the same active moiety (i.e., different forms of the same active ingredient) to be the same when dissolution, solubility, and absorption are shown to be equivalent." (Letter from the Center for Drug Evaluation and Research, Coleman Decl., Exh. D at 4).

The contested patents are for different anhydrous polymorphs of terazosin hydrochloride. As stated above, different polymorphic forms containing the same active ingredient may be considered by the FDA as equivalents. However, this is the case only if the dissolution, solubility and absorption of the polymorphs are [*33] the same. It is not clear that these factors are consistent as between Hytrin and the later patents. Accordingly, a question of fact exists as to whether the later Abbott polymorphs are covered by Hytrin. There is simply not enough undisputed information before this Court for it to decide under the summary judgment standard whether a dihydrate version of terazosin hydrochloride covers anhydrous polymorphs that differ only in crystalline structure. In the event these polymorphs do have the same dissolution, solubility and absorption as that found within the drug substance in Hytrin, their patents would likely be construed as properly claiming the drug substance in Hytrin and the listing of those patents would be correct. However, if these polymorphs are found not to claim the drug substance in Hytrin, they could not likely claim to be covered by that drug substance and would then not be entitled to listing in the Orange Book. Those issues cannot presently be resolved summarily. Accordingly, Zenith's motion for partial summary judgment is denied.

CONCLUSION

For the foregoing reasons, defendant's motion to dismiss is denied, and plaintiff's motion for partial summary judgment [*34] is also denied.

JOHN W. BISSELL

United States District Judge

DATED: August 5, 1996

ORDER

For the reasons set forth in the Court's Opinion filed herewith,

It is on this 5th day of August, 1996

ORDERED that defendant's motion to dismiss plaintiff's complaint be, and it hereby is, denied; and it is further

ORDERED that plaintiff's motion for partial summary judgment be, and it hereby is, denied.

JOHN W. BISSELL

United States District Judge